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Introduction

This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

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Date: xx/xx/20xx	Document: **ISO/DIS xxxx**

1	2	(3)	4	5	(6)	(7)
MB	**Clause No./ Subclause No./Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/Note**	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

ISO/DIS 9000

ISO/TC **176**/SC **1**

Secretariat: **ANSI**

Voting begins on:
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2014-10-10

Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

ICS: 03.120.10;01.040.03

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9000 was prepared by Technical Committee ISO/TC 176, *TC Quality management and quality assurance*, Subcommittee SC 1, *SC Concepts and terminology*.

This fourth edition cancels and replaces the third edition (ISO 9000:2005).

Introduction

This International Standard provides the fundamentals and terminology of quality management systems. It is the foundation of other ISO quality management system standards and serves as the normative reference for many of them. It will help the user to understand the principles, systems model and terminology of quality management in order to more effectively and efficiently implement a quality management system and realize value from other ISO quality management system standards.

This management standard for quality makes the case for a well-defined quality management system based on a framework that integrates established quality fundamental concepts, principles, processes and resources to help organizations realize their goals Its aim is to make top management aware of their duties and commitment in achieving their customers and stakeholders needs, expectations and satisfaction with their products and services.

The terms and definitions are arranged in conceptual order according to ISO/IEC Directives. Annex A provides information on how this works, including the set of diagrams of the concept systems that form the concept ordering. An alphabetical list is provided at the end of the document to aid location of entries.

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes the fundamental concepts, principles and vocabulary of quality management, and defines related terms, which are universally applicable to the following:

- organizations seeking sustained success through the implementation of quality and other management systems;
- customers seeking confidence in organization's ability to provide satisfactory products;
- organizations seeking confidence in their supply chain that their product requirements will be met;
- those interested parties seeking to improve communication through a common understanding of the terminology used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- those providing training in quality management;
- developers of related standards.

2 Quality management principles and fundamental concepts

2.1 General

The quality management concepts and principles described in this standard give management the capacity to meet challenges presented by an environment that is profoundly different from that of just a few decades ago. The context in which the 21st century organisation works is characterised by accelerated change, globalisation of markets, limited resources, and the emergence of knowledge as a principal resource. Society has become better educated and more demanding, making interested parties increasingly more powerful. This clause provides a way of thinking about the organisation more broadly, by providing fundamental concepts and principles to be used in the development of a Quality Management System.

2.2 Fundamental concepts

2.2.1 Quality

Quality focused organizations embrace a culture that inspires and drives behaviour, attitude, actions and processes in order to deliver value through fulfilling the requirements of interested parties.

The quality of an organization's products and services is determined by not only the ability to satisfy a particular customer but also the intended and unintended impact on other interested parties.

The quality of products and services include not only their intended function, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

Quality management systems manage the interacting processes, sub-systems, procedures, and resources required to:

- provide value to all relevant interested parties, and
- realize the outputs, outcomes, or results of the whole organization

Anticipating the impact of outcomes is essential in managing performance.

Quality management systems provide a means of managing the cost of quality. Awareness of these costs enables organizations to take action in order to optimise utilization of resources.

2.2.3 Interested parties

Organizations learn from relevant interested parties to develop their purpose and thereby define what outputs, outcomes, or results they need to deliver to those interested parties and to society in general.

Organizations attract, capture and retain the support of organizations and individuals they depend upon for their success.

2.2.4 Context of an organization

An adaptable, open and agile organization understands its context through examination of internal and external issues impacting its purpose and sustainability. In addition to financial performance, organizations may take environmental and social responsibility into account. An organization's purpose is expressed through statements such as an organization's Vision and mission, policies, and improvement objectives.

2.2.5 Management Support

Active engagement and management support for the quality management system enables:

- the provision of adequate human and other resources,
- monitoring processes and outcomes,
- identifying risks and opportunities, and
- taking appropriate and robust actions.

Responsible acquisition, deployment, maintenance and disposal of resources satisfy the organization's objectives.

People are one of the most important resources of the organization. The performance of the organization is dependent upon how people behave within the system in which they work. A quality management system is more effective when management and individuals understand and develop the competence needed to perform their roles and responsibilities.

2.2.5.1 Awareness

People within an organization should be aligned through a common understanding of the organization's desired outcomes and how they are driven by the quality policy. Awareness is evident when individuals understand how their role contributes to the achievement of an organization's objectives.

2.2.5.2 Communication

Effective communication throughout the organization and relevant interested parties enhances involvement through better understanding of:

- the management system and its performance, and
- organizational values, objectives and strategies.

2.3 Quality management principles

2.3.1 General

The following seven quality management principles are derived from the fundamental concepts described in Sub-clause 2.1 as principles of action.

2.3.2 Customer focus

2.3.2.1 Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2.3.2.2 Rationale

Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of the organization.

2.3.2.3 Key benefits

Some key benefits are:

- Increased customer value;
- Increased customer satisfaction;
- Improved customer loyalty;
- Enhanced repeat business;
- Enhanced reputation of the organization;
- Expanded customer base;
- Increased revenue and market share.

2.3.2.4 Actions you can take

Some actions you can take are:

- Recognize direct and indirect customers as those who receive value from the organization.
- Understand customers' current and future needs and expectations.
- Link the organization's objectives to customer needs and expectations.
- Communicate customer needs and expectations throughout the organization.
- Plan, design, develop, produce, deliver and support goods and services to meet customer needs and expectations.
- Measure and monitor customer satisfaction and take appropriate actions.
- Determine and take actions on interested parties' needs and expectations that can affect customer satisfaction.
- Actively manage relationships with customers to achieve sustained success.

2.3.3 Leadership

2.3.3.1 Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

2.3.3.2 Rationale

Creation of unity of purpose and direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

2.3.3.3 Key benefits

Some key benefits are:

- Increased effectiveness and efficiency in meeting the organization's quality objectives;
- Better coordination of the organization's processes;

- Improved communication between levels and functions of the organization;
- Development and improvement of the capability of the organization and its people to deliver desired results.

2.3.3.4 Actions you can take

Some actions you can take are:
- Communicate the organization's mission, vision, strategy, policies and processes throughout the organization;
- Create and sustain shared values, fairness and ethical models for behavior at all levels of the organization;
- Establish a culture of trust and integrity;
- Encourage an organization-wide commitment to quality;
- Ensure that leaders at all levels are positive examples to people in the organization;
- Provide people with the required resources, training and authority to act with accountability;
- Inspire, encourage and recognize people's contribution.

2.3.4 Engagement of people

2.3.4.1 Statement

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization’s capability to create and deliver value.

2.3.4.2 Rationale

To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization’s quality objectives.

2.3.4.3 Key benefits

Some key benefits are:
- Improved understanding of the organization’s quality objectives by people in the organization and increased motivation to achieve them;
- Enhanced involvement of people in improvement activities;
- Enhanced personal development, initiatives and creativity;
- Enhanced people satisfaction;
- Enhanced trust and collaboration throughout the organization;
- Increased attention to shared values and culture throughout the organization.

2.3.4.4 Actions you can take

Some actions you can take are:
- Communicate with people to promote understanding of the importance of their individual contribution;
- Promote collaboration throughout the organization;
- Facilitate open discussion and sharing of knowledge and experience;
- Empower people to determine constraints to performance and to take initiatives without fear;
- Recognize and acknowledge people’s contribution, learning and improvement;
- Enable self-evaluation of performance against personal objectives;
- Conduct surveys to assess people’s satisfaction, communicate the results, and take appropriate actions.

2.3.5 Process approach

2.3.5.1 Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

2.3.5.2 Rationale

The quality management system consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

2.3.5.3 Key benefits

Some key benefits are:

- Enhanced ability to focus effort on key processes and opportunities for improvement;
- Consistent and predictable outcomes through a system of aligned processes;
- Optimized performance through effective process management, efficient use of resources, and reduced cross-functional barriers;
- Enabling the organization to provide confidence to interested parties as to its consistency, effectiveness and efficiency.

2.3.5.4 Actions you can take

Some actions you can take are:

- Define objectives of the system and processes necessary to achieve them;
- Establish authority, responsibility and accountability for managing processes;
- Understand the organization’s capabilities and determine resource constraints prior to action;
- Determine process interdependencies and analyze the effect of modifications to individual processes on the system as a whole;
- Manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently;
- Ensure the necessary information is available to operate and improve the processes and to monitor, analyze and evaluate the performance of the overall system;
- Manage risks which can affect outputs of the processes and overall outcomes of the quality management system.

2.3.6 Improvement

2.3.6.1 Statement

Successful organizations have an ongoing focus on improvement.

2.3.6.2 Rationale

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

2.3.6.3 Key benefits

Some key benefits are:

- Improved process performance, the organization’s capabilities and customer satisfaction;
- Enhanced focus on root cause investigation and determination, followed by prevention and corrective actions;
- Enhanced ability to anticipate and react to internal and external risks and opportunities;
- Enhanced consideration of both incremental and breakthrough improvement;

- Improved use of learning for improvement;
- Enhanced drive for innovation.

2.3.6.4 Actions you can take

Some actions you can take are:
- Promote establishment of improvement objectives at all levels of the organization;
- Educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;
- Ensure people are competent to successfully promote and complete improvement projects;
- Develop and deploy processes to implement improvement projects throughout the organization;
- Track, review and audit the planning, implementation, completion and results of improvement projects;
- Integrate improvement consideration into development of new or modified goods and services and processes;
- Recognize and acknowledge improvement.

2.3.7 Evidence-based decision making

2.3.7.1 Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

2.3.7.2 Rationale

Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.

2.3.7.3 Key benefits

Some key benefits are:
- Improved decision making processes;
- Improved assessment of process performance and ability to achieve objectives;
- Improved operational effectiveness and efficiency;
- Increased ability to review, challenge and change opinions and decisions;
- Increased ability to demonstrate the effectiveness of past decisions.

2.3.7.4 Actions you can take

Some actions you can take are:
- Determine, measure and monitor key indicators to demonstrate the organization’s performance;
- Make all data needed available to the relevant people;
- Ensure that data and information are sufficiently accurate, reliable and secure;
- Analyze and evaluate data and information using suitable methods;
- Ensure people are competent to analyze and evaluate data as needed;
- Make decisions and take actions based on evidence, balanced with experience and intuition.

2.3.8 Relationship management

2.3.8.1 Statement

For sustained success, organizations manage their relationships with interested parties, such as suppliers.

2.3.8.2 Rationale

Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner networks is of particular importance.

2.3.8.3 Key benefits

Some key benefits are:

- Enhanced performance of the organization and its interested parties through responding to the opportunities and constraints related to each interested party;
- Common understanding of goals and values among interested parties;
- Increased capability to create value for interested parties by sharing resources and competence and managing quality related risks;
- A well-managed supply chain that provides a stable flow of goods and services.

2.3.8.4 Actions you can take

Some actions you can take are:

- Determine relevant interested parties (such as suppliers, partners, customers, investors, employees, and society as a whole) and their relationship with the organization;
- Determine and prioritize interested party relationships that need to be managed;
- Establish relationships that balance short-term gains with long-term considerations;
- Pool and share information, expertise and resources with relevant interested parties;
- Measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives;
- Establish collaborative development and improvement activities with suppliers, partners and other interested parties;
- Encourage and recognize improvements and achievements by suppliers and partners.

2.4 Development of fundamentals into a QMS

2.4.1 QMS model

Organisations share the characteristics of humans as a living and learning social organism.

2.4.1.1 System

Humans use their senses to identify, engage with, understand, and adapt to their environment in order to conduct their every-day activities and achieve fulfilment. Organisations also seek to understand their environment and identify those whose needs and expectations that must be satisfied to achieve the organisation's objective of sustained success. Although appearing the same and often comprising similar sub-systems and processes, every organisation, like every human being, is unique.

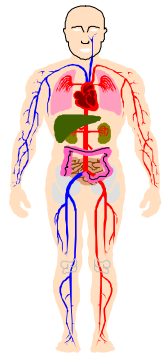

Figure 1 – The human being as a system

2.4.1.2 Process

Human beings comprise sub-systems and processes, such as the respiratory and digestive systems. Although each sub-system can be individually identified, defined, measured and improved, it is the way in which they work together that sustains life.

The organisation also has sub-systems and processes that can be identified individually, measured and improved. Consistent with human beings, it is the way in which those sub-systems and processes interact that determines the outcomes necessary to achieve sustained success. Some sub-systems and processes may be critical while others may not. This is analogous to a vital organ, in that without its proper functioning the organism will die.

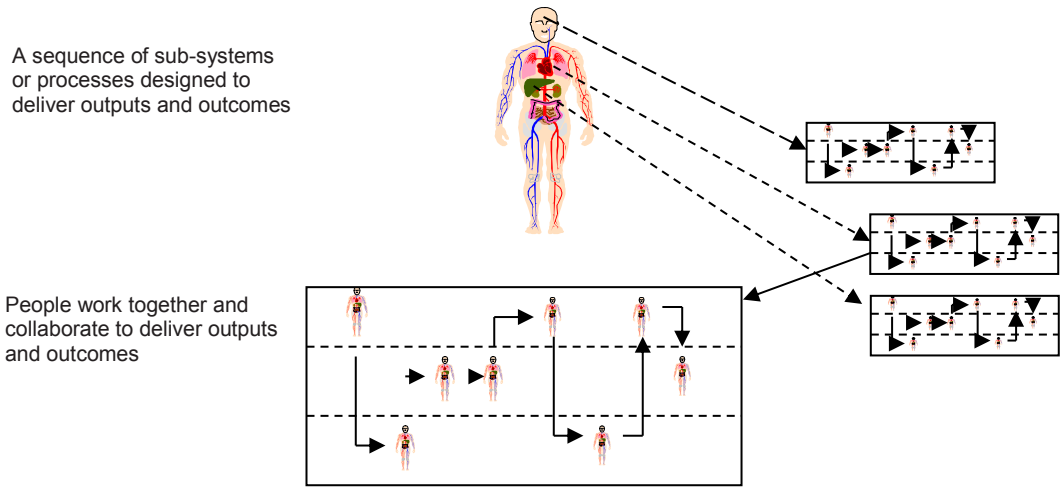

Figure 2 – System and process interface

2.4.1.3 Activity

The same people who collaborate to create and operate a process carry out their day to day activities within these processes. Some of those activities are pre-defined while others just happen as a result of an individual's understanding of the vision, values and objectives of the organisation, or reaction to external stimuli.

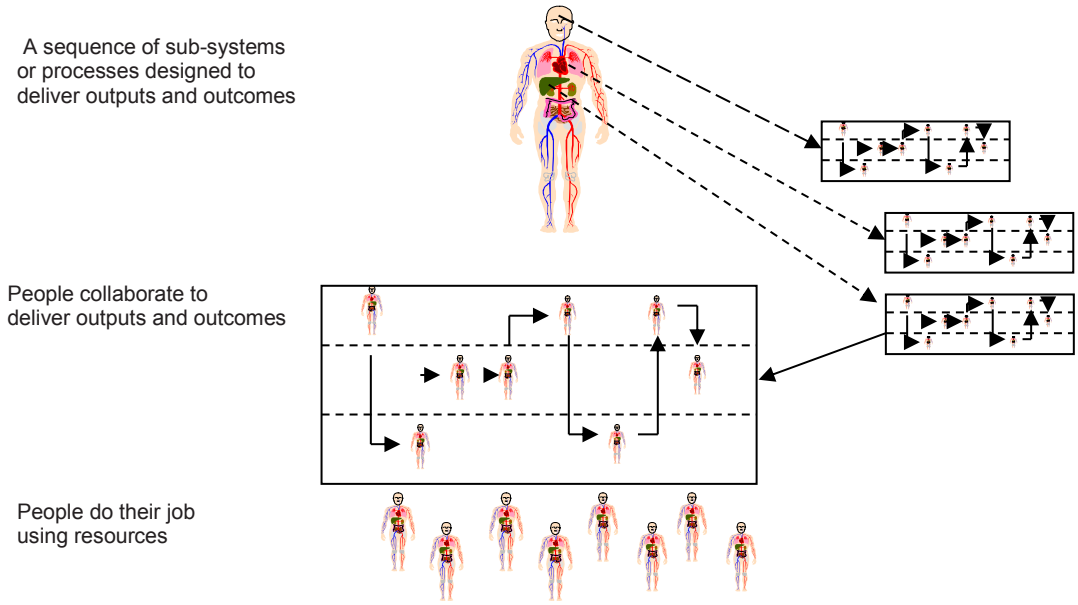

Figure 3 – The anatomy of quality management system

Human beings as a species have adapted to their environment to survive. Sometimes improvements may not be enough: organizations may use disruptive innovations to achieve the dramatic changes required to be successful.

2.4.2 Development of QMS

A Quality Management System is a dynamic living system that evolves over time through periods of improvement and innovation. Every organization has quality management activities, whether they have been formally planned or not. This document provides guidance on how to develop a formal system to manage these activities. It is not necessary to dismiss activities which already exist in the organization, ISO 9000 and ISO 9001 can be used to provide a structure that helps the organization to develop a cohesive quality management system.

A formal Quality Management System provides a framework for planning, executing, monitoring and improving the performance of quality management activities. The Quality Management System doesn't need to be complicated; rather it should accurately reflect the needs of the organization. In developing the Quality Management System, the fundamental concepts and principles given in this document can provide valuable guidance.

Planning for a Quality Management System is critical for organizations to achieve their objectives. Planning is not a singular event, rather it is an ongoing process. Plans evolve as the organization learns and circumstances change. A plan should take into account all quality activities of the organization and ensure that it covers all guidance of ISO 9000 and requirements of ISO 9001. The plan is implemented upon approval.

It is important for an organization to regularly monitor and evaluate both the implementation of the plan and the performance of the Quality Management System. Carefully considered indicators facilitate these monitoring and evaluation activities. Actions should be taken for correction and improvement based on analysis of the evidence gathered. The knowledge gained may lead to innovation, taking Quality Management System performance to higher levels.

Organizations need to have full knowledge of the causal relations between planning activities and control measures. There are many methods and models in literature to describe the development of a quality management system. One common methodology, known as PDCA, may be used to illustrate the planning,

executing, monitoring and improvement activities. It is important to plan (P), execute according to the plan (D), monitor the results (C) and improve the plan as necessary (A).

PDCA may be used during three levels of performance:

1) Maintenance: Take action to maintain performance at current levels, meeting objectives.
2) Improvement: Take action to raise performance to a higher level, meeting or exceeding objectives.
3) Innovation: Take action to fundamentally transform performance, by generating and utilizing new knowledge.

It is important to address the three levels with proper balance to effectively and efficiently achieve an organization's purpose and objectives. Addressing only maintenance may not realize the potential ability of the organization's processes. Likewise, attention to improvement and innovation without steady maintenance may not retain the desired results. An ideal status can be achieved by addressing all three levels.

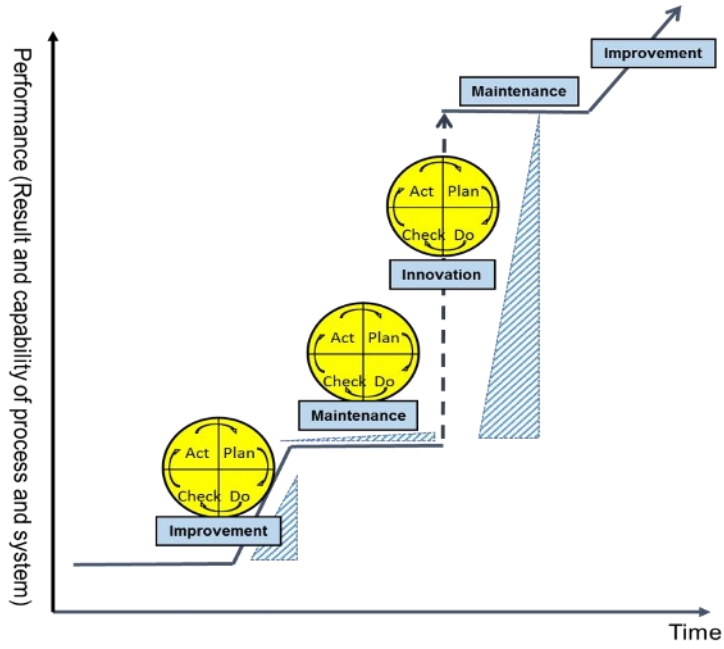

Figure 4 - QMS: three levels of performance

2.4.3 Relationship to other standards

The 21st century organisation is more complex than its predecessors and more difficult to manage, principally because it must function in an environment that few could have contemplated a few years ago. Organisations are currently not able to achieve success by standing alone.

In the past, many issues such as innovation, ethics, trust and reputation could be regarded as individual parameters excluded from day-to-day management. Success in today's organisational environment requires that these issues be given constant attention and considered as interrelated. This standard recognises and is a response to this new management context by providing common guidance for standards such as ISO 9001:2015, ISO 14001, ISO 50001 and ISO 26000.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

A term referred to in a definition or note which is defined elsewhere in this clause is indicated by italic font followed by its entry number in parentheses in regular font. These terms shall be replaceable by their definition without major change to the sense of the definition or the sentence in which it appears (10).

For example:

document (3.8.4) is defined as "*information* (3.8.1.1) and the medium on which it is contained";

information (3.8.1.1) is defined as **"**meaningful *data* (3.8.1)".

If the term "information" (3.8.1.1) is replaced by its definition, as follows:

document (3.8.4) then becomes "meaningful data and the medium on which it is contained".

A concept limited to a special meaning in a particular context is indicated by designating the subject field in angle brackets, <>, before the definition.

EXAMPLE In the context of an *audit* (3.10.1), the term entry for technical expert is:

3.2.3
technical expert
<*audit*> (3.10.1) person who provides specific *knowledge* (3.8.3) or expertise to the *audit team* (3.10.5)

This vocabulary contains terms from all the quality management systems standards developed and published by ISO/TC 176 current at the time of the publication of this standard. The terms and definitions are arranged in conceptual order according to ISO/IEC directives and have an alphabetical list at the end of the document to aid location of entries.

3.1 Terms related to person or people

3.1.1
top management
person or group of people who directs and controls an *organization* (3.2.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.2.1).

Note 2 to entry: If the scope of the *management system* (3.4.3) covers only part of an *organization* (3.2.1) then top management refers to those who direct and control that part of the *organization* (3.2.1).

3.1.2
involvement
engagement in, and contribution to, shared *objectives* (3.7.1)

[ISO 10018: 2012]

3.1.3
people involvement
involvement (2.1.2) of people through the provision of responsibility and authority to achieve desired results

[ISO 10018:2012 It is recommended that this entry be deleted at the next revision of this document]

3.1.4
dispositioning authority
<configuration management> person or a group of persons assigned responsibility and authority to make decisions on the *configuration* (3.12.6)

Note 1 to entry: Dispositioning authority can also be called a “configuration control board”.

Note 2 to entry: Relevant *interested parties* (3.2.4) within and outside the *organization* (3.2.1) should be represented on the dispositioning authority.

3.1.5
quality management system consultant
person who assists the *organization* (3.2.1) on *quality management system realization* (3.6.4), giving advice or *information* (3.8.2)

NOTE 1 to entry: The consultant can also assist in realizing parts of a *quality management system* (3.4.4).

NOTE 2 to entry: ISO 10019 provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

[ISO 10019]

3.2 Terms related to organization

3.2.1
organization
person or group of people that has its own *functions* (3.2.6) with responsibilities, authorities and relationships to achieve its *objectives* (3.7.1)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, *association* (3.2.2), charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.2.2
association
<customer satisfaction> *organization* (3.2.1) consisting of member organizations or persons

[10003:2007] [Upon revision of this standard it is recommended to delete or revise this term entry]

3.2.3
organizational structure
arrangement of responsibilities, authorities and relationships between people

Note 1 to entry: A formal expression of the organizational structure is often provided in a *quality manual* (3.8.9) or a *quality plan* (3.8.10) for a *project* (3.6.2).

Note 2 to entry: The scope of an organizational structure can include relevant interfaces to external *organizations* (3.2.1).

3.2.4
context of the organization
business environment
combination of internal and external factors and conditions that can have an effect on an organization's approach to its *products* (3.7.6), *services* (3.7.7), investments and *interested parties* (3.2.5)

Note 1 to entry: The concept of context of the organization is equally applicable to not-for-profit or public service *organizations* (3.2.1) as it is to those seeking profits.

Note 2 to entry: In English this concept is often referred to by other phrases such as business environment, organizational environment or ecosystem of an *organization* (3.2.1).

3.2.5
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.2.1) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

EXAMPLE *Customers* (3.2.8), owners, people in an *organization* (3.2.1), *suppliers* (3.2.9), bankers, unions, partners or society that may include competitors or opposing pressure groups.

3.2.6
function
role to be carried out by a designated unit of the *organization* (3.2.1)

3.2.7
metrological function
function (3.2.6) with administrative and technical responsibility for defining and implementing the *measurement management system* (3.4.7)

3.2.8
customer
person or organization that could or does receive a *product* (3.7.6) or a *service* (3.7.7) that is intended for or required by this person or organization

EXAMPLES Consumer, client, end-user, retailer, input to internal *process* (3.6.1), beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the *organization* (3.2.1). Customers outside of the organization are external customers. The *output* (3.7.5) of each internal *process* (3.6.1) is the input of the next *process.* The next *process* is the internal customer of the preceding *process*.

3.2.9
supplier
provider
person or *organization* (3.2.1) that provides a *product* (3.7.6) or a *service* (3.7.7)

EXAMPLE Producer, distributor, retailer or vendor of *a product* (3.7.6) or a *service* (3.7.6) or *information* (3.8.2)

Note 1 to entry: A supplier can be internal or external to the *organization* (3.2.1).

Note 2 to entry: In a contractual situation, a supplier is sometimes called "contractor".

3.2.10
external supplier
external provider

supplier (3.2.9) that is extraneous to the *organization* (3.2.1)

EXAMPLE Producer, distributor, retailer or vendor of a *product* (3.7.6) or a *service* (3.7.7) or *information* (3.8.2).

3.2.11
provider
<customer satisfaction> person or organization that supplies and operates an external dispute resolution process

3.2.12
dispute resolution process provider
DRP-provider
person or *organization* (3.2.1) that supplies and operates an external *dispute* (3.9.7) resolution *process* (3.6.1)

Note 1 to entry: Generally, a DRP-provider is a legal entity, separate from the *organization* (3.2.1) or person as an individual and the complainant. In this way, the attributes of independence and fairness are emphasized. In some situations, a separate unit is established within the *organization* to handle unresolved *complaints* (3.9.4).

Note 2 to entry: The DRP-provider *contracts* (3.6.8) with the parties to provide *dispute* (3.9.7) resolution, and is accountable for *performance* (3.7.9). The DRP-provider supplies *dispute resolvers* (3.9.8). The DRP-provider also utilizes support, executive and other managerial staff to supply financial resources, clerical support, scheduling assistance, training, meeting rooms, supervision and similar *functions* (3.2.6).

Note 3 to entry: DRP-Providers can take many forms including not-for-profit, for-profit and public entities. An *association* (3.2.2) can also be a *provider* (3.2.11).

Note 4 to entry: In ISO 10003:2007 instead of the term DRP-provider, the term “provider” is used.

3.3 Terms related to activity

3.3.1
improvement
activity to enhance *performance* (3.7.9)
Note to entry: Improvement can be achieved by a recurring or by a singular activity

3.3.2
continual improvement
recurring activity to enhance *performance* (3.7.9)

Note 1 to entry: The *process* (3.6.1) of establishing *objectives* (3.7.1) and finding opportunities for *improvement* (3.3.1) is a continual *process* through the use of *audit findings* (3.10.16) and *audit conclusions* (3.10.17), analysis of *data* (3.8.1), *management* (3.3.3) *reviews* (3.13.2) or other means and generally leads to *corrective action* (3.11.2) or *preventive action* (3.11.1).

3.3.3
management
coordinated activities to direct and control an *organization* (3.2.1)

Note 1 to entry: Management can include establishing *policies* (3.4.8) and *objectives* (3.7.1) and *processes* (3.6.1) to achieve these objectives.

Note 2 to entry: The term “management” sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an *organization* (3.2.1). When “management” is used

in this sense, it should always be used with some form of qualifier to avoid confusion with the concept of "management" as a set of activities defined above. For example, "management shall…" is deprecated whereas "*top management* (3.1.1) shall…" is acceptable. Otherwise different words should be adopted to convey the concept when related to people e.g. managerial or managers.

3.3.4
quality management
management (3.3.3) with regard to *quality* (3.5.2)

Note 1 to entry: Quality management generally includes establishment of the *quality policy* (3.4.9) and *quality objectives* (3.7.2), *quality planning* (3.3.5), *quality control* (3.3.8), *quality assurance* (3.3.6) and *quality improvement* (3.3.7).

3.3.5
quality planning
part of *quality management* (3.3.4) focused on setting *quality objectives* (3.7.2) and specifying necessary operational *processes* (3.6.1) and related resources to fulfil the *quality objectives* (3.7.2)

Note 1 to entry: Establishing *quality plans* (3.8.10) can be part of quality planning.

3.3.6
quality assurance
part of *quality management* (3.3.4) focused on providing confidence that *quality requirements* (3.5.5) will be fulfilled

3.3.7
quality improvement
part of *quality management* (3.3.4) focused on increasing the ability to fulfil *quality requirement*s (3.5.5)

Note 1 to entry: The *quality requirements* (3.5.5) can be related to any aspect such as *effectiveness* (3.7.11) , *efficiency* (3.7.10) or *traceability* (3.5.13)

3.3.8
quality control
part of *quality management* (3.3.14) focused on fulfilling *quality requirements* (3.5.5)

3.3.9
configuration management
coordinated activities to direct and control *configuration* (3.12.6)

Note 1 to entry: Configuration management generally concentrates on technical and organizational activities that establish and maintain control of a *product* (3.7.6) or *service* (3.7.7) and its configuration information throughout the life cycle of the *product*.

3.3.10
change control
<configuration management> activities for control of the *output* (3.7.5) after formal approval of its *product configuration information* (3.5.8)

3.3.11
activity
<project management > smallest identified item of work in a *project* (3.6.2)

3.3.12
project management
planning, organizing, *monitoring* (3.13.3), controlling and reporting of all aspects of a *project* (3.6.2) and the motivation of all those involved in it to achieve the *project* (3.6.2) *objectives* (3.7.1)

3.3.13
configuration item
entity within a *configuration* (3.12.6) that satisfies an end use *function* (3.2.6)

3.4 Terms related to system

3.4.1
system
set of interrelated or interacting elements

3.4.2
infrastructure
<organization> *system* (3.4.1) of facilities, equipment and *services* (3.7.7) needed for the operation of an *organization* (3.2.1)

3.4.3
management system
set of interrelated or interacting elements of an *organization* (3.2.1) to establish *policies* (3.4.8) and *objectives* (3.7.1) and *processes* (3.6.1) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines e.g. *quality management* (3.3.4), financial management or environmental management.

Note 2 to entry: The management system elements establish the *organization's* (3.2.1) structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, *objectives* (3.7.1) and *processes* (3.6.1),etc.to achieve those objectives.

Note 3 to entry: The scope of a *management system* (3.4.3) may include the whole of the *organization* (3.2.1), specific and identified *functions* (3.2.6) of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.4.4
quality management system
management system (3.4.3) with regard to *quality* (3.5.2)

3.4.5
work environment
set of conditions under which work is performed

Note 1 to entry: Conditions can include physical, social, psychological and environmental factors (such as temperature, recognition schemes, occupational stress, ergonomics and atmospheric composition).

3.4.6
metrological confirmation
set of operations required to ensure that *measuring equipment* (3.13.9) conforms to the *requirements* (3.5.4) for its intended use

Note 1 to entry: Metrological confirmation generally includes calibration or verification, any necessary adjustment or *repair* (3.11.9), and subsequent recalibration, comparison with the metrological *requirements* (3.5.4) for the intended use of the equipment, as well as any required sealing and labelling.

Note 2 to entry: Metrological confirmation is not achieved until and unless the fitness of the *measuring equipment* (3.13.9) for the intended use has been demonstrated and documented.

679 Note 3 to entry: The *requirements* (3.5.4) for intended use include such considerations as range, resolution
680 and maximum permissible errors.

681 Note 4 to entry: Metrological requirements are usually distinct from, and are not specified in, *product* (3.7.16)
682 *requirements* (3.5.4).

683 **3.4.7**
684 **measurement management system**
685 set of interrelated and interacting elements necessary to achieve metrological confirmation and continual
686 control of *measurement processes* (3.13.8)

687 **3.4.8**
688 **policy**
689 <organization> intentions and direction of an *organization* (3.2.1) as formally expressed by its *top*
690 *management* (3.1.1)

691 **3.4.9**
692 **quality policy**
693 *policy* (3.4.5) related to *quality* (3.5.2)

694 Note 1 to entry: Generally the quality policy is consistent with the overall *policy* (3.4.8) of the *organization*
695 (3.2.1), can be aligned with the organization's *vision* (3.4.10) and *mission* (3.4.11) and provides a framework
696 for the setting of *quality objectives* (3.7.2).

697 Note 2 to entry: *Quality management* (3.3.4) principles presented in this International Standard can form a
698 basis for the establishment of a *quality policy* (3.4.9).

699 **3.4.10**
700 **vision**
701 <organization's own future> aspiration of what an *organization* (3.2.1) would like to become as expressed by
702 *top management* (3.1.1)

703 **3.4.11**
704 **mission**
705 <organization> *organization's* (3.2.1) purpose for existing as expressed by *top management* (3.1.1)

706 **3.4.12**
707 **strategy**
708 planned activities to achieve an *objective* (3.7.1).

709

710 ## 3.5 Terms related to requirement

711 **3.5.1**
712 **object**
713 entity
714 anything perceivable or conceivable

715 [ISO 1087-1:2000]

716 EXAMPLES *Product* (3.7.16), *service* (3.7.7), *process* (3.6.1), person, *organization* (3.2.1), *system* (3.4.1),
717 resource.

718 Note 1 to entry: Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g.
719 conversion ratio, a project plan) or imagined (e.g. a unicorn).

3.5.2
quality
degree to which a set of inherent *characteristics* (3.12.1) of an *object* (3.5.1) fulfils *requirements* (3.5.4)

Note 1 to entry: The term “quality” can be used with adjectives such as poor, good or excellent.

Note 2 to entry: “Inherent”, as opposed to “assigned”, means existing in the *object* (3.5.1).

3.5.3
grade
category or rank given to different *quality requirements* (3.5.5) for an *object* (3.5.1) having the same functional use

EXAMPLE Class of airline ticket and category of hotel in a hotel brochure.

Note 1 to entry: When establishing a *quality requirement* (3.5.5), the grade is generally specified.

3.5.4
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: “Generally implied” means that it is custom or common practice for the *organization* (3.2.1) and *interested parties* (3.2.5) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.8.3).

[Annex SL Appendix 3, 3.03 of the ISO/IEC Directives Part 2:2012]

Note 3 to entry: A qualifier can be used to denote a specific type of requirement e.g. *product* (3.7.6) *requirement* (3.5.4), *quality management* (3.3.4) requirement, *customer* (3.2.8) requirement, *quality requirement* (3.5.4.1).

Note 4 to entry: Requirements can be generated by different *interested parties* (3.2.5).

Note 5 to entry: It can be necessary for achieving high *customer satisfaction* (3.9.3) to fulfil an expectation of a *customer* (3.2.8) even if it is neither stated nor generally implied or obligatory.

3.5.5
quality requirement
requirement (3.5.4) related to *quality* (3.5.2)

3.5.6
statutory requirement
obligatory *requirement* (3.5.4) specified by a legislative body

3.5.7
regulatory requirement
obligatory *requirement* (3.5.4) specified by an authority mandated by a legislative body

3.5.8
product configuration information
requirement (3.5.4) for *product* (3.7.6) design, realization, *verification* (3.8.13), operation and support

3.5.9
nonconformity
non-fulfilment of a *requirement* (3.5.4)

760 [Annex SL 3.19]

761 **3.5.10**
762 **defect**
763 nonconformity (3.5.9) related to an intended or specified use

764 Note 1 to entry: The distinction between the concepts defect and *nonconformity* (3.5.9) is important as it has
765 legal connotations, particularly those associated with *product* (3.7.6) *and service* (3.7.7) liability issues.

766 Note 2 to entry: The intended use as intended by the *customer* (3.2.8) can be affected by the nature of the
767 *information* (3.8.2), such as operating or maintenance instructions, provided by the *supplier* (3.2.9).

768 **3.5.11**
769 **conformity**
770 fulfilment of a *requirement* (3.5.4)

771 [Annex SL 3.18]

772 Note 1 to term: In English the word “conformance” is synonymous but deprecated. In French the word
773 “compliance” is synonymous but deprecated.

774 **3.5.12**
775 **capability**
776 ability of an *object* (3.5.1) to realize an *output* (3.7.5) that will fulfil the *requirements* (3.5.4) for that output

777 Note 1 to entry: Process capability terms in the field of statistics are defined in ISO 3534-2.

778 **3.5.13**
779 **traceability**
780 ability to trace the history, application or location of an *object* (3.5.1)

781 Note 1 to entry: When considering *a product (3.7.6) or a service* (3.7.7), *traceability* (3.5.13) can relate to:

782 - the origin of materials and parts;
783 - the processing history; and
784 - the distribution and location of the *product* (3.7.6) *or service* (3.7.7) after delivery.

785 Note 2 to entry: In the field of metrology the definition in ISO/IEC GUIDE 99: 2007, is the accepted definition.

786 **3.5.14**
787 **dependability**
788 availability *performance* (3.7.9) of an *object* (3.5.1) under specified conditions

789

790 3.6 Terms related to process

791 **3.6.1**
792 **process**
793 set of interrelated or interacting activities which transforms inputs into *output*s (3.7.5)

794 Note 1 to entry: Inputs to a process are generally *output*s (3.7.5) of other processes.

795 Note 2 to entry: In some processes, some inputs become *output*s (3.7.5) without any transformation e.g. a
796 blueprint used in a manufacturing process or a catalyst in a chemical process.

Note 3 to entry: Processes in an *organization* (3.2.1) are generally planned and carried out under controlled conditions to add value.

Note 4 to entry: A process where the *conformity* (3.5.11) of the resulting *output* (3.7.5) cannot be readily or economically validated is frequently referred to as a "special process".

3.6.2
project
unique *process* (3.6.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an *objective* (3.7.1) conforming to specific *requirements* (3.5.4), including the constraints of time, cost and resources

Note 1 to entry: An individual project can form part of a larger project structure.

Note 2 to entry: In some projects the *objectives* (3.7.1) are refined and the *product (3.7.6) or service* (3.7.7) *characteristics* (3.12.1) defined progressively as the project proceeds.

Note 3 to entry: The *output (3.7.5)* of a project can be one or several units of *product* (3.7.6) or *service* (3.7.7).

Note 4 to entry: The project's *organization* (3.2.1) is normally temporary and established for the lifetime of the project.

Note 5 to entry: The complexity of the interactions among project activities is not necessarily related to the project size

3.6.3
innovation
process (3.6.1) resulting in a new or substantially changed *object* (3.5.1)

Note 1 to entry: The *object* (3.5.1) for the purpose of innovation can be e.g. a *management system* (3.4.3), a *process* (3.6.1), a *product* (3.7.6), *a service* (3.7.7) or technology.

3.6.4
quality management system realization
process (3.6.1) of establishing, documenting, implementing, maintaining and continually improving a *quality management system* (3.4.4)

Note 1 to entry: Quality management system realization can include the following:

a) identifying the *processes* (3.6.1) needed for a *quality management system* (3.4.4) and their application throughout the *organization* (3.2.1);

b) determining the sequence and interaction of the identified *processes* (3.6.1);

c) determining criteria and methods needed to ensure that both the operation and control of the identified *processes* (3.6.1) are effective;

d) ensuring the availability of resources and *information* (3.8.2) necessary to support the operation and *monitoring* (3.13.3) of the identified *processes* (3.6.1);

e) *monitoring*, (3.13.3) measuring and analyzing the identified *processes* (3.6.1);

f) implementing actions necessary to achieve planned results and *continual improvement* (3.3.2) of the identified *processes* (3.6.1)

[ISO 10019]

3.6.5
competence acquisition
process (3.6.1) of attaining *competence* (3.6.10)

[Modifications recommended for revision of ISO 10018:2012]

3.6.6
procedure
specified way to carry out an activity or a *process* (3.6.1)

Note 1 to entry: Procedures can be documented or not.

3.6.7
outsource (verb)
make an arrangement where an external *organization* (3.2.1) performs part of an *organization's (3.2.1) function* (3.2.6) or *process* (3.6.1)

Note 1 to entry: An external *organization* (3.2.1) is outside the scope of the *management system* (3.4.3), although the outsourced *function* (3.2.6) or *process* (3.6.1) is within the scope.

3.6.8
contract
binding agreement

3.6.9
design and development
set of processes (3.6.1) that transforms *requirements* (3.5.4) for an *object* (3.5.1) into more detailed *requirements* (3.5.4)

Note 1 to entry: The *requirements* (3.5.4) forming input to design and development can be expressed in a broader, more general sense than the requirements forming the *output* (3.7.5) of design and development. In a *project* (3.6.2) there can be several design and development stages.

Note 2 to entry: In English the words "design" and "development" and the term "design and development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development. In French the words "conception" and "development" and the term "conception et development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development.

Note 3 to entry: A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. *product* (3.7.6) design and development or *process* (3.6.1) design and development.

3.6.10
competence
ability to apply *knowledge* (3.8.6) and skills to achieve intended results

Note 1 to entry: Demonstrated *competence* (3.6.10) is sometimes referred to as qualification.

3.7 Terms related to results

3.7.1
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, *organization* (3.2.1)-wide, *project* (3.6.6.1), *product* (3.7.3.1) and *process* (3.6.1).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a *quality* (3.5.2) *objective* (3.7.1) or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *quality management systems* (3.4.1.4) *quality objectives* (3.7.2) are set by the *organization* (3.2.1), consistent with the *quality policy* (3.4.9), to achieve specific results.

3.7.2
quality objective
objective (3.7.1) related to *quality* (3.5.2)

Note 1 to entry: Quality objectives are generally based on the *organization*'s (3.2.1) *quality policy* (3.4.9).

Note 2 to entry: Quality objectives are generally specified for relevant *functions* (3.2.6) and levels in the *organization* (3.2.1).

3.7.3
success
<organization> achieving an *objective* (3.7.1)

Note 1 to entry: The success of an *organization* (3.2.1) emphasizes the need for a balance between its economic or financial interests and the needs of its *interested parties* (3.2.5), such as *customers* (3.2.8), users, investors / shareholders (owners), people in the *organization*, *suppliers* (3.2.9), partners, interest groups and communities.

3.7.4
sustained success
<organization> *success* (3.7.3) over a period of time

Note 1 to entry: Sustained success emphasizes the need for a balance between economic-financial interests of an *organization* (3.2.1) and those of the social and ecological environment.

Note 2 to entry: Sustained success relates to the *interested parties* (3.2.5) of an *organization* (3.2.1) such as *customers* (3.2.8), owners, people in an *organization*, *suppliers* (3.2.9), bankers, unions, partners or society.

3.7.5
output
result of a *process* (3.6.1)

Note 1 to entry “output”: There are four generic output categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many outputs comprise elements belonging to different generic output categories. Whether the output is then called service, product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

Note 2 to entry “output”: The ownership of a product can usually be transferred. This is not necessarily the case for a service.

3.7.6
product
output (3.7.5) that is a result of activities where none of them necessarily is performed at the interface between the *provider* (3.2.9) and the *customer* (3.2.8)

Note 1 to entry "product": Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

3.7.7
service
intangible *output* (3.7.5) that is the result of at least one activity necessarily performed at the interface between the provider and the customer

Note 1 to entry "service": Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. a car to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants);

A service is usually experienced by the customer.

3.7.8
risk
effect of uncertainty on an expected result

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.8.2) related to, understanding or *knowledge* (3.8.6) of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential *events* (ISO Guide 73, 3.5.1.3) and *consequences* (ISO Guide 73, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated *likelihood* (ISO Guide 73, 3.6.1.1) of occurrence.

Note 5 to entry: The term "risk" is sometimes used when there is only the possibility of negative consequences

3.7.9
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the *management* (3.3.3) of activities, *processes* (3.6.1), *product* (3.7.6) and *services* (3.7.7), *systems* (3.4.1) or *organizations* (3.2.1).

[Modifications recommended for revision of ISO 10018:2012]

3.7.10
efficiency
relationship between the result achieved and the resources used

3.7.11
effectiveness
extent to which planned activities are realized and planned results achieved

3.8 Terms related to data, information and document

3.8.1
data
facts about an *object* (3.5.1)

3.8.2
information
meaningful *data* (3.8.1)

3.8.3
documented information
information (3.8.2) required to be controlled and maintained by an *organization* (3.2.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

g) the quality *management system* (3.4.3, including related *processes* (3.6.1);

h) *information* (3.8.2) created in order for the *organization* (3.2.1) to operate (documentation);

i) evidence of results achieved (*records* (3.8.11)

[Annex SL 3.11]

3.8.4
objective evidence
data (3.8.1) supporting the existence or verity of something

Note 1 to entry: Objective evidence may be obtained through observation, *measurement* (3.13.7), *test* (3.13.5), or other means.

Note 2 to entry: Objective evidence for the purpose of *audit* (3.10.1) generally consists of *records* (3.8.11), statements of fact or other *information* (3.8.2) which are relevant to the *audit criteria* (3.10.14) and verifiable

3.8.5
information system
<QMS> network of communication channels used within an *organization* (3.2.1)

3.8.6
knowledge
available collection of *information* (3.8.2) being a justified belief and having a high certainty to be true

3.8.7
document
information (3.8.2) and the medium on which it is contained

EXAMPLE *Record* (3.8.11), *specification* (3.8.8), *procedure* (3.6.6) *document* (3.8.7) drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or combination thereof.

Note 2 to entry: A set of documents, for example *specifications* (3.8.8) and *records* (3.8.11), is frequently called “documentation”.

Note 3 to entry: Some *requirements* (3.5.4) (e.g. the *requirement* to be readable) relate to all types of documents, however there can be different *requirements* (3.5.4) for *specifications* (3.8.8) (e.g. the requirement to be revision controlled) and for *records* (3.8.11) (e.g. the *requirement* to be retrievable).

3.8.8
specification
document (3.8.7) stating *requirements* (3.5.4)

EXAMPLE *Quality manual* (3.8.9), *quality plan* (3.8.10), technical drawing, procedure document, work instruction

Note 1 to entry: A specification can be related to activities (e.g. procedure document, process specification and test specification), or *products* (3.7.6) (e.g. *product* (3.7.6) *specification* (3.8.8) *performance* (3.7.9) specification and drawing).

Note 2 to entry: It can be, that by stating *requirements* (3.5.4) a specification additionally is stating results achieved by *design and development* (3.6.9) and thus in some cases can be used as a *record* (3.8.11).

3.8.9
quality manual
specification (3.8.8) for the *quality management system* (3.4.4) of an *organization* (3.2.1)

Note 1 to entry: Quality manuals can vary in detail and format to suit the size and complexity of an individual *organization* (3.2.1).

3.8.10
quality plan
specification (3.8.8) of the *procedures* (3.6.6) and associated resources that shall be applied by when and by whom to a specific *object* (3.5.1)

Note 1 to definition: These *procedures* (3.6.6) generally include those referring to *quality management* (3.3.4) *processes* (3.6.1) and to *product* (3.7.6) realization processes.

Note 2 to entry: A quality plan often makes reference to parts of the *quality manual* (3.8.9) or to procedure *documents* (3.8.7).

Note 3 to entry: A quality plan is generally one of the results of *quality planning* (3.3.2.5).

3.8.11
record
document (3.8.7) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.5.13) and to provide evidence of *verification* (3.8.13), *preventive action* (3.11.1) and *corrective action* (3.11.2).

Note 2 to entry: Generally records need not be under revision control.

3.8.12
project management plan
document (3.8.7) specifying what is necessary to meet the *objective(s)* (3.7.1) of the *project* (3.6.2)

Note 1 to entry: A project management plan should include or refer to the *project's* (3.6.2) *quality plan* (3.8.10).

Note 2 to entry: The project management plan also includes or references such other plans as those relating to organizational structures, resources, schedule, budget, *risk* (3.7.8) *management* (3.3.3), environmental management, health and safety *management* (3.3.3) and security *management* (3.3.3), as appropriate

3.8.13
verification
confirmation, through the provision of *objective evidence* (3.8.4), that specified *requirements* (3.5.4) have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an *inspection* (3.13.4) or of other forms of *determination* (3.13.1) such as performing alternative calculations or reviewing *documents* (3.8.7)

Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process* (3.6.1)

Note 3 to entry: The word "verified" is used to designate the corresponding status.

3.8.14
validation
confirmation, through the provision of objective evidence, that the *requirements* (3.5.4) for a specific intended use or application have been fulfilled

Note 1 to entry: The *objective evidence* (3.8.4) needed for a validation is the result of a *test* (3.13.5) or other form of *determination* (3.13.1) such as performing alternative calculations or reviewing *documents* (3.8.7)

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

3.8.15
configuration status accounting
formalized recording and reporting of product configuration *information* (3.8.2), the status of proposed changes and the status of the implementation of approved changes

3.8.16
specific case
<quality plan> subject of the *quality plan* (3.8.10)

Note 1 to entry: This term is used to avoid repetition of "*process* (3.6.1), *product* (3.7.6), *project* (3.6.2) or *contract* (3.6.8)" within ISO 10005.

[ISO 10005, 3.10]

3.9 Terms related to customer

3.9.1

customer
(See definition in 3.2.8)

3.9.2
feedback
<customer satisfaction> opinions, comments and expressions of interest in a product, a service or a complaints-handling process

3.9.3
customer satisfaction
customer's (3.2.8) perception of the degree to which the customer's expectations have been fulfilled

Note 1 to entry: It can be that the *customer's* (3.2.8) expectation is not known to the *organization* (3.2.1), or even to himself/herself until the *product* (3.7.6) or *service* (3.7.7) is delivered. It can be necessary for achieving high *customer satisfaction* (3.9.3) to fulfil an expectation of a *customer* even if it is neither stated nor generally implied or obligatory.

Note 2 to entry: *Complaints* (3.9.4) are a common indicator of low *customer satisfaction* (3.9.3) but their absence does not necessarily imply high *customer satisfaction*.

Note 3 to entry: Even when *customer* (3.2.8) *requirements* (3.5.4) have been agreed with the *customer* and fulfilled, this does not necessarily ensure high *customer satisfaction* (3.9.3).

Note 4 to entry: See ISO 10004, *Quality Management — Customer satisfaction — Guidelines for monitoring and measuring*.

3.9.4
complaint
<customer satisfaction> expression of dissatisfaction made to an *organization* (3.3.1), related to its *product* (3.7.6) or *service* (3.7.7), or the complaints-handling *process* (3.6.1) itself, where a response or resolution is explicitly or implicitly expected

3.9.5
customer service
interaction of the *organization* (3.2.1) with the *customer* (3.2.8) throughout the life cycle of a product or a service

3.9.6
customer satisfaction code of conduct
code
promises made to *customers* (3.2.8) by an *organization* (3.2.1) concerning its behavior, that are aimed at enhanced *customer satisfaction* (3.9.3), and related provisions

Note 1 to entry: Related provisions can include *objectives* (3.7.1), conditions, limitations, contact *information* (3.8.2), and *complaints* (3.9.4) handling *procedures* (3.6.6).

Note 2 to entry: In ISO 10001:2007 the term "code" is used instead of "customer satisfaction code of conduct."

3.9.7
dispute
<customer satisfaction> disagreement, arising from a *complaint* (3.9.4), submitted to a *provider* (3.2.9)

Note 1 to entry: Some *organizations* (3.2.1) allow their *customers* (3.2.8) to express their dissatisfaction to a *provider* (3.2.9) in the first instance. In this situation, the expression of dissatisfaction becomes a *complaint* (3.9.4) when sent to the *organization* for a response, and becomes a dispute if not resolved by the *organization* without *provider* intervention. Many *organizations* prefer their *customers* to first express any dissatisfaction to the *organization* before utilizing dispute resolution external to the *organization*.

3.9.8
dispute resolver
<customer satisfaction> individual assigned by a *provider* (3.2.9) to assist the parties in resolving a *dispute* (3.9.7)

EXAMPLES: Staff, volunteer, *contract* (3.6.8) personnel.

3.10 Terms related to audit

3.10.1
audit
systematic, independent and documented *process* (3.6.1) for obtaining *objective evidence* (3.10.15) and evaluating it objectively to determine the extent to which the *audit criteria* (3.10.14) are fulfilled

[Annex SL 3.17 – the reference to "audit evidence" in that definition is replaced with "objective evidence" (3.10.15) to prevent a circularity in this standard between the definitions of "audit evidence" and "audit criteria" and to that extent also differs from ISO 19011:2012]

Note 1 to entry: The fundamental elements of an audit include the *determination* (3.13.1) of the *conformity* (3.5.11) of an *object* (3.5.1) according to a *procedure* (3.6.6) carried out by personnel not being responsible for the *object* (3.5.1) audited

Note 2 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a *combined audit* (3.10.2) or a *joint audit* (3.10.3).

Note 3 to entry: Internal audits, sometimes called first-party audits are conducted by, or on behalf of, the *organization* (3.2.1) itself for *management* (3.3.3) *review* (3.13.2) and other internal purposes, and may form the basis for an *organization's* declaration of *conformity* (3.5.11). In many cases, particularly in smaller *organizations*, independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 4 to entry: External audits include those generally called second and third-party audits. Second party audits are conducted by parties having an interest in the *organization* (3.2.1), such as *customers* (3.2.8), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing *organizations* such as those providing certification/registration of *conformity* (3.5.11) to ISO 9001 or ISO 14001.

3.10.2
combined audit
audit (3.10.1) carried out together on two or more *management systems* (3.4.3)

3.10.3
joint audit
audit (3.10.1) carried out at a single auditee by two or more auditing *organizations* (3.2.1)

3.10.4
audit client
organization or person requesting an *audit* (3.10.1)

3.10.5
auditee
organization (3.2.1) being audited

3.10.6
guide
<audit> (3.10.1) person appointed by the *auditee* (3.10.5) to assist the *audit team* (3.10.7)

3.10.7
audit team
one or more *auditors* (3.10.8) conducting an *audit* (3.10.1), supported if needed by *technical experts* (3.10.9)

Note 1 to entry: One *auditor* (3.10.8) of the audit team is appointed as the audit team leader.

Note 2 to entry: The audit team may include auditors-in-training.

3.10.8
auditor
person who conducts an *audit* (3.10.1)

3.10.9
technical expert
<audit> person who provides specific *knowledge* (3.8.6) or expertise to the *audit team* (3.10.7)

Note 1 to entry: Specific *knowledge* (3.8.6) or expertise relates to the *organization* (3.2.1), the *process* (3.6.1) or activity to be audited, or language or culture.

Note 2 to entry: A technical expert does not act as an *auditor* (3.10.8) in the *audit team* (3.10.7).

3.10.10
observer
<audit> person who accompanies the audit team but does not audit

Note 1 to entry: An observer can be a member of the *auditee* (3.10.5), a regulator or other interested party (3.2.5) who witnesses the *audit* (3.10.1).

3.10.11
audit programme
set of one or more *audits* (3.6.1) planned for a specific time frame and directed towards a specific purpose

3.10.12
audit scope
extent and boundaries of an *audit* (3.10.1)

Note 1 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and *processes* (3.6.1).

3.10.13
audit plan
description of the activities and arrangements for an *audit* (3.10.1)

3.10.14
audit criteria
set of *policies* (3.4.8), *procedures* (3.6.6) or *requirements* (3.5.4) used as a reference against which *audit evidence* (3.10.15) is compared

3.10.15
objective / **audit evidence**
records, statements of fact or other information, which are relevant to the audit criteria and verifiable

3.10.16
audit findings
results of the evaluation of the collected *audit evidence* (3.10.15) against *audit criteria* (3.10.14)

Note 1 to entry: Audit findings indicate *conformity* (3.5.11) or *nonconformity* (3.5.9).

Note 2 to entry: Audit findings can lead to the identification of opportunities for *improvement* (3.3.1) or recording good practices.

Note 3 to entry: In English, if the *audit criteria* (3.10.14) are selected from *statutory requirements* (3.5.6) or *regulatory requirements* (3.5.7), the audit finding can be called compliance or non-compliance.

3.10.17
audit conclusion
outcome of an *audit* (3.10.1), after consideration of the *audit* (3.10.1) *objectives* (3.7.1) and all *audit findings* (3.10.16)

3.11 Terms related to action

3.11.1
preventive action
action to eliminate the cause of a potential *nonconformity* (3.5.9) or other undesirable potential situation

Note 1 to definition: There can be more than one cause for a potential *nonconformity* (3.5.9).

Note 2 to entry: Preventive action is taken to prevent occurrence whereas *corrective action* (3.11.2) is taken to prevent recurrence.

3.11.2
corrective action
action to eliminate the cause of a *nonconformity* (3.5.9) and to prevent recurrence

Note 1 to definition: There can be more than one cause for a nonconformity (3.5.9).

Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* (3.11.1) is taken to prevent occurrence.

[Annex SL 3.21]

3.11.3
correction
action to eliminate a detected *nonconformity* (3.5.9)

Note 1 to entry: A correction can be made in conjunction with a *corrective action* (3.11.2).

Note 2 to entry: A correction can be, for example, *rework* (3.11.8) or *regrade* (3.11.4).

[Annex SL 3.20]

3.11.4
regrade
alteration of the *grade* (3.5.3) of a *nonconforming* (3.5.9) *product* (3.7.6) or *service* (3.7.7) in order to make it conform to *requirements* (3.5.4) differing from the initial requirements

3.11.5
concession
permission to use or *release* (3.11.7) a *product* (3.7.6) or *service* (3.7.7) that does not conform to specified *requirements* (3.5.4)

Note 1 to entry: A concession is generally limited to the delivery of *products* (3.7.6) and *services* (3.7.7) that have *nonconforming* (3.5.9) *characteristics* (3.12.1) within specified limits and is generally given for a limited quantity of products and services *f*or period of time, and for a specific use.

3.11.6
deviation permit
permission to depart from the originally specified *requirements* (3.5.4) of a *product* (3.7.6) or *service* (3.7.7) prior to its realization

Note 1 to entry: A deviation permit is generally given for a limited quantity of *products* (3.7.6) and *services* (3.7.7) or period of time, and for a specific use.

3.11.7
release
permission to proceed to the next stage of a *process* (3.6.1)

Note 1 to entry: In English, in the context of software and *documents* (3.8.7), the word “release” is frequently used to refer to a version of the *software* or the *document* itself.

3.11.8
rework
action on a *nonconforming* (3.5.9) *product* (3.7.6) or *service* (3.7.7) to make it conform to the *requirements* (3.5.4)

Note 1 to entry: Rework can affect or change parts of the *nonconforming* (3.5.9) *product* (3.7.6).

3.11.9
repair
action on a *nonconforming* (3.5.9) *product* (3.7.6) or *service* (3.7.7) to make it acceptable for the intended use

Note 1 to entry: A successful repair of a *nonconforming* (3.5.9) *product* (3.7.6) does not necessarily make the *product* conform to the *requirements* (3.5.4). It can be that in conjunction with a repair a *concession* (3.11.5) is required.

Note 2 to entry: Repair includes remedial action taken on a previously conforming *product* (3.7.6) to restore it for use, for example as part of maintenance.

Note 3 to entry: Repair *can* affect or change parts of the *nonconforming* (3.5.9) *product* (3.7.6).

3.11.10
scrap
action on a nonconforming *product* (3.7.6) or *service* (3.7.7) to preclude its originally intended use

EXAMPLE Recycling, destruction

Note 1 to entry: In a nonconforming *service* (3.7.7) situation, use is precluded by discontinuing the *service*.

3.12 Terms related to characteristic

3.12.1
characteristic
distinguishing feature

Note 1 to entry: A characteristic can be inherent or assigned.

Note 2 to entry: A characteristic can be qualitative or quantitative.

Note 3 to entry: There are various classes of characteristic, such as the following:

a) physical (e.g. mechanical, electrical, chemical or biological characteristics);
b) sensory (e.g. related to smell, touch, taste, sight, hearing);
c) behavioural (e.g. courtesy, honesty, veracity);
d) temporal (e.g. punctuality, reliability, availability).
e) ergonomic (e.g. physiological characteristic, or related to human safety);
f) functional (3.5.7) (e.g. maximum speed of an aircraft).

3.12.2
quality characteristic
inherent *characteristic* (3.12.1) of an *object* (3.5.1) related to a *requirement* (3.5.4)

Note 1 to definition: Inherent means existing in something, especially as a permanent *characteristic* (3.12.2).

Note 2 to entry: A *characteristic* (3.12.2) assigned to an *object* (3.5.1) (e.g. the price of an *object*) is not a quality characteristic of that *object*).

3.12.3
performance indicator
performance metric
characteristic (3.12.1) having significant impact on realization of the *output* (3.7.5) and *customer satisfaction* (3.9.3)

EXAMPLES *Nonconformities* (3.5.9) per million opportunities, first time *capability* (3.5.12), *nonconformities* (3.5.9) per unit.

Note 1 to entry: The *characteristic* (3.12.1) can be quantitative or qualitative

3.12.4
human factor
characteristic (3.12.1) of a person having an impact on an *object* (3.5.1) under consideration

Note 1 to entry: *Characteristics* (3.12.1) can be physical, cognitive or social.

Note 2 to entry: Human factors can have a significant impact on a *management system* (3.4.3).

3.12.5
metrological characteristic
characteristic (3.12.1) which can influence the results of *measurement* (3.13.7)

Note 1 to entry: *Measuring equipment* (3.13.9) usually has several metrological characteristics.

Note 2 to entry: Metrological characteristics can be the subject of calibration.

3.12.6
configuration
interrelated *functional* (3.2.6) and physical *characteristics* (3.12.1) of a *product* (3.7.6) defined in *product configuration information* (3.5.4.4)

3.12.7
configuration baseline
approved *product configuration information* (3.5.8) that establishes the *characteristics* (3.12.1) of a *product* (3.7.6) at a point in time that serves as reference for activities throughout the life cycle of the *product* (3.7.6) or *service* (3.7.7)

3.13 Terms related to determination

3.13.1
determination
activity to find out one or more *characteristics* (3.12.1) and their *characteristic* (3.12.1) values

3.13.2
review
determination (3.13.1) of the suitability, adequacy or e*ffectiveness* (3.7.11) of an *object* (3.5.1) to achieve established *objectives* (3.7.1)

EXAMPLE *Management* (3.3.3) review, design and development review, review of *customer* (3.2.8) *requirements* (3.5.4), *nonconformity* (3.5.9) review and peer review.

Note to 1 entry: Review can also include the *determination* (3.13.1) of *efficiency* (3.7.10).

3.13.3
monitoring
determining (3.13.1) the status of a *system* (3.4.3), a *process* (3.6.1) or an activity

Note 1 to entry: To determine the status there may be a need to check, supervise or critically observe.

Note 2 to entry: Monitoring is generally a *determination* (3.13.1) of the *object* (3.5.1) being monitored, carried out at different stages or at different times

3.13.4
inspection
determination (3.13.1) of *conformity* (3.5.11) to specified *requirements* (3.5.4)

Note 1 to entry: If the result of an inspection shows *conformity* (3.5.11), it can be used for purposes of *verification* (3.8.13).

Note 2 to entry: The result of an inspection can show *conformity* (3.5.11) or *nonconformity* (3.5.9) or a degree of *conformity* (3.5.11).

3.13.5
test
determination (3.13.1) according to *requirements* (3.5.4) for a specific intended use or application

Note 1 to entry: If the result of a test shows *conformity* (3.5.11), it can be used for purposes of *validation* (3.8.14).

3.13.6
progress evaluation
<project management> assessment of progress made on achievement of the *project* (3.6.2) *objectives* (3.7.1)

Note 1 to definition: This assessment should be carried out at appropriate points in the *project* (3.6.1.1) life cycle across *project* (3.6.2) *processes* (3.6.1), based on criteria for *project* (3.6.2) *processes* (3.6.1) and *product* (3.7.6).

Note 2 to entry: The results of progress evaluations may lead to revision of the *project management plan* (3.8.12).

3.13.7
measurement
process (3.6.1) to determine a value

Note 1 to entry: According to ISO 3534-2:2006 the value determined is generally the value of a quantity.

3.13.8
measurement process
set of operations to determine the value of a quantity

3.13.9
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement process* (3.13.8)

Annex A
(informative)

Methodology used in the development of the vocabulary

A.1 Introduction

The universality of application of the ISO 9000 series of standards requires the use of:

— a technical description but without the use of technical language; and
— a coherent and harmonized vocabulary that is easily understandable by all potential users of quality management systems standards.

Concepts are not independent of one another, and an analysis of the relationships between concepts within the field of quality management systems and the arrangement of them into concept systems is a prerequisite of a coherent vocabulary. Such an analysis was used in the development of the vocabulary specified in this document. Since the concept diagrams employed during the development process may be helpful in an informative sense, they are reproduced in A.4.

A.2 Content of a vocabulary entry and the substitution rule

The concept forms the unit of transfer between languages (including variants within one language, for example American English and British English). For each language, the most appropriate term for the universal transparency of the concept in that language, i.e. not a literal approach to translation, is chosen.

A definition is formed by describing only those characteristics that are essential to identify the concept. Information concerning the concept which is important but which is not essential to its description is put in one or more notes to the definition.

When a term is substituted by its definition, subject to minor syntax changes, there should be no change in the meaning of the text. Such a substitution provides a simple method for checking the accuracy of a definition. However, where the definition is complex in the sense that it contains a number of terms, substitution is best carried out taking one or, at most, two definitions at a time. Complete substitution of the totality of the terms will become difficult to achieve syntactically and unhelpful in conveying meaning.

A.3 Concept relationships and their graphical representation

A.3.1 General

In terminology work, the relationships between concepts are based on the hierarchical formation of the characteristics of a species so that the most economical description of a concept is formed by naming its species and describing the characteristics that distinguish it from its parent or sibling concepts.

There are three primary forms of concept relationships indicated in this annex: generic (A.3.2), partitive (A.3.3) and associative (A.3.4).

A.3.2 Generic relation

Subordinate concepts within the hierarchy inherit all the characteristics of the superordinate concept and contain descriptions of these characteristics which distinguish them from the superordinate (parent) and coordinate (sibling) concepts, e.g. the relation of spring, summer, autumn and winter to season.

Generic relations are depicted by a fan or tree diagram without arrows (see Figure A.1).

Example from ISO 704:2009 (5.5.2.2.1)

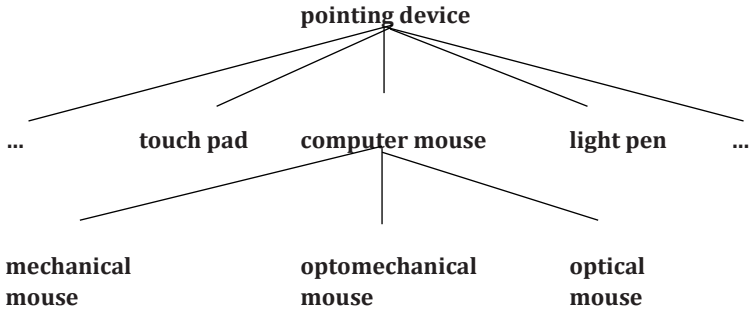

Figure A.1 — Graphical representation of a generic relation

A.3.3 Partitive relation

Subordinate concepts within the hierarchy form constituent parts of the superordinate concept, e.g. spring, summer, autumn and winter may be defined as parts of the concept year. In comparison, it is inappropriate to define sunny weather (one possible characteristic of summer) as part of a year.

Partitive relations are depicted by a rake without arrows (see Figure A.2). Singular parts are depicted by one line, multiple parts by double lines.

Example adapted from ISO 704:2009 (5.5.2.3.1)

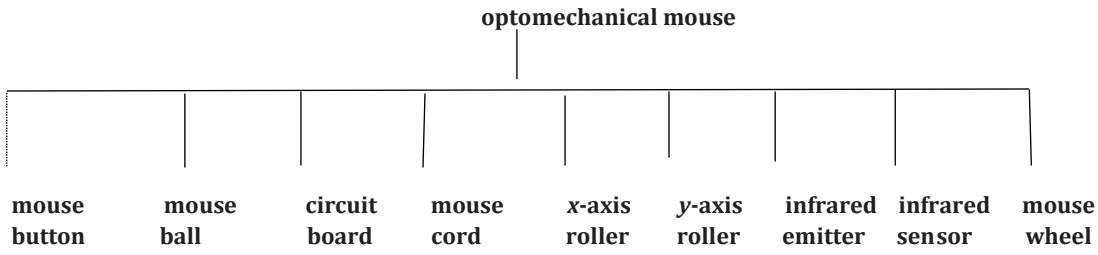

Figure A.2 — Graphical representation of a partitive relation

A.3.4 Associative relation

Associative relations cannot provide the economies in description that are present in generic and partitive relations but are helpful in identifying the nature of the relationship between one concept and another within a concept system, e.g. cause and effect, activity and location, activity and result, tool and function, material and product.

Associative relations are depicted by a line with arrowheads at each end (see Figure A.3).

Example from ISO 704:2009 (5.6.2)

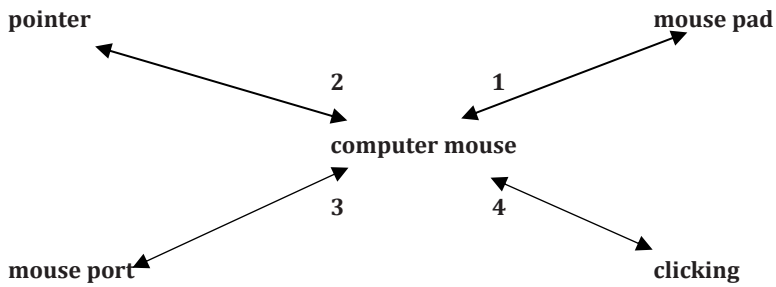

Figure A.3 — Graphical representation of an associative relation

A.4 Concept diagrams

Figures A.4 to A.16 show the concept diagrams on which the thematic groupings of Clause 3 are based.

Since the definitions of the terms are repeated without any related notes, it is recommended to refer to Clause 3 to consult any such notes.

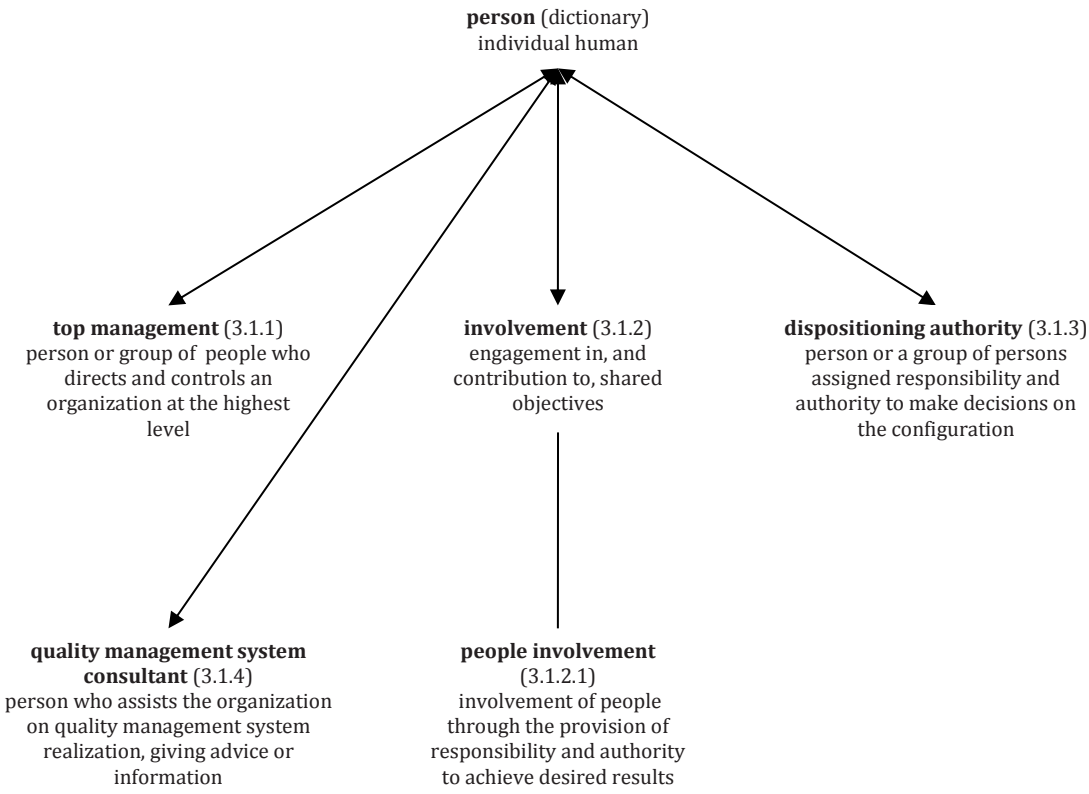

Figure A.4 – 3.1 Concepts of the class person or people and related concepts
For more information see notes in Clause 3

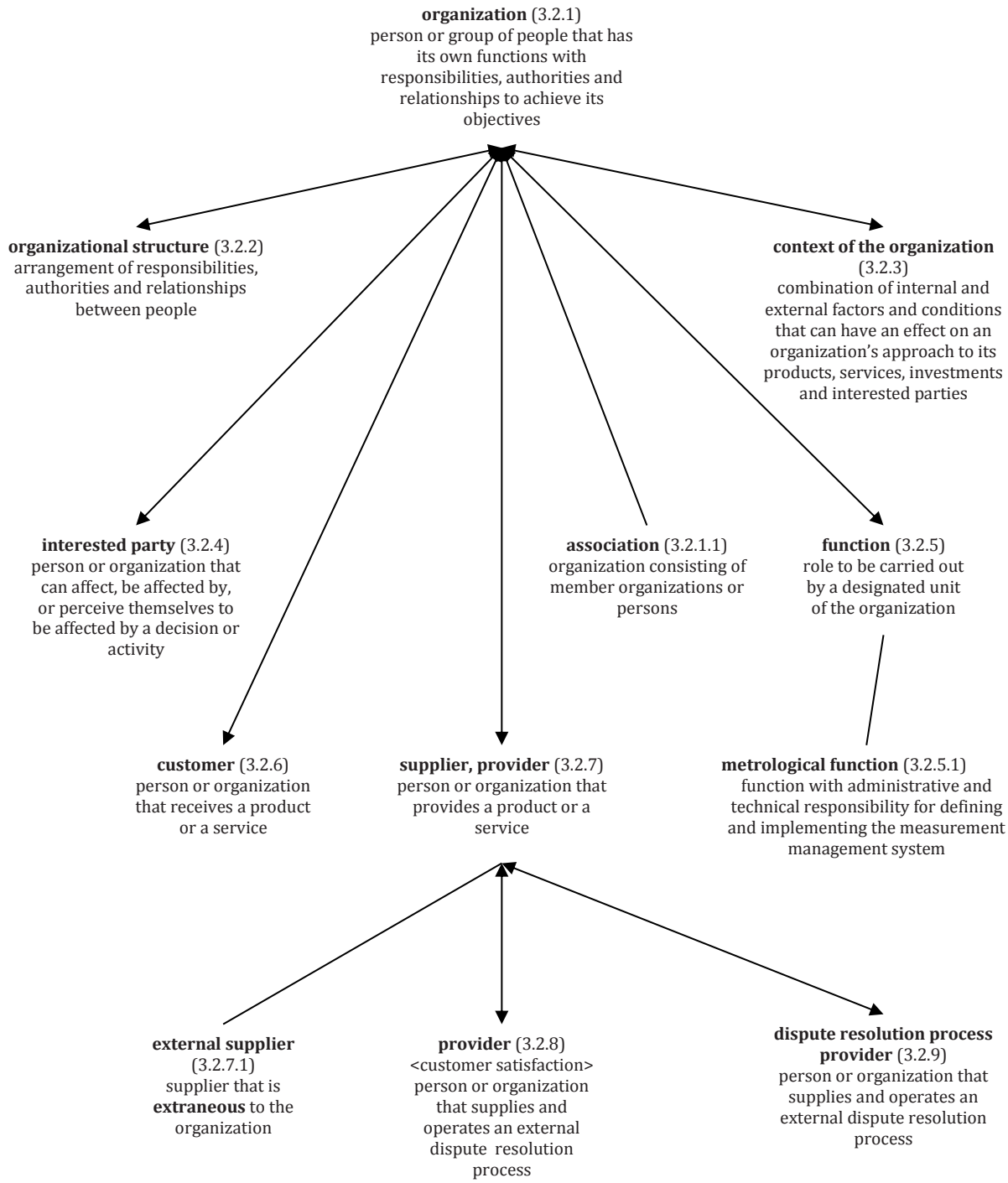

Figure A.5 — 3.2 Concepts of the class organization and related concepts
For more information see notes in Clause 3

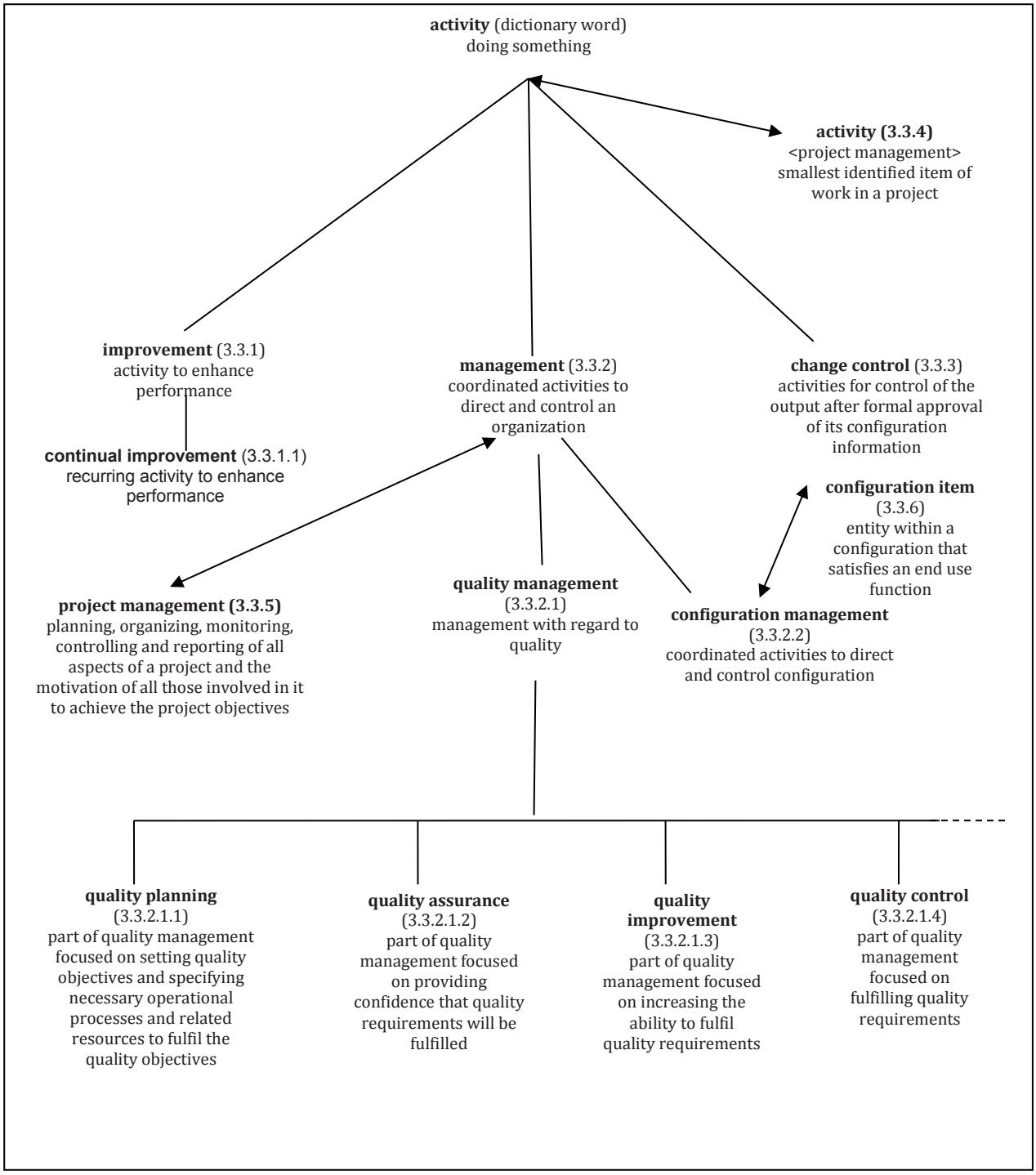

Figure A.6 — 3.3 Concepts of the class activity and related concepts
For more information see notes in Clause 3

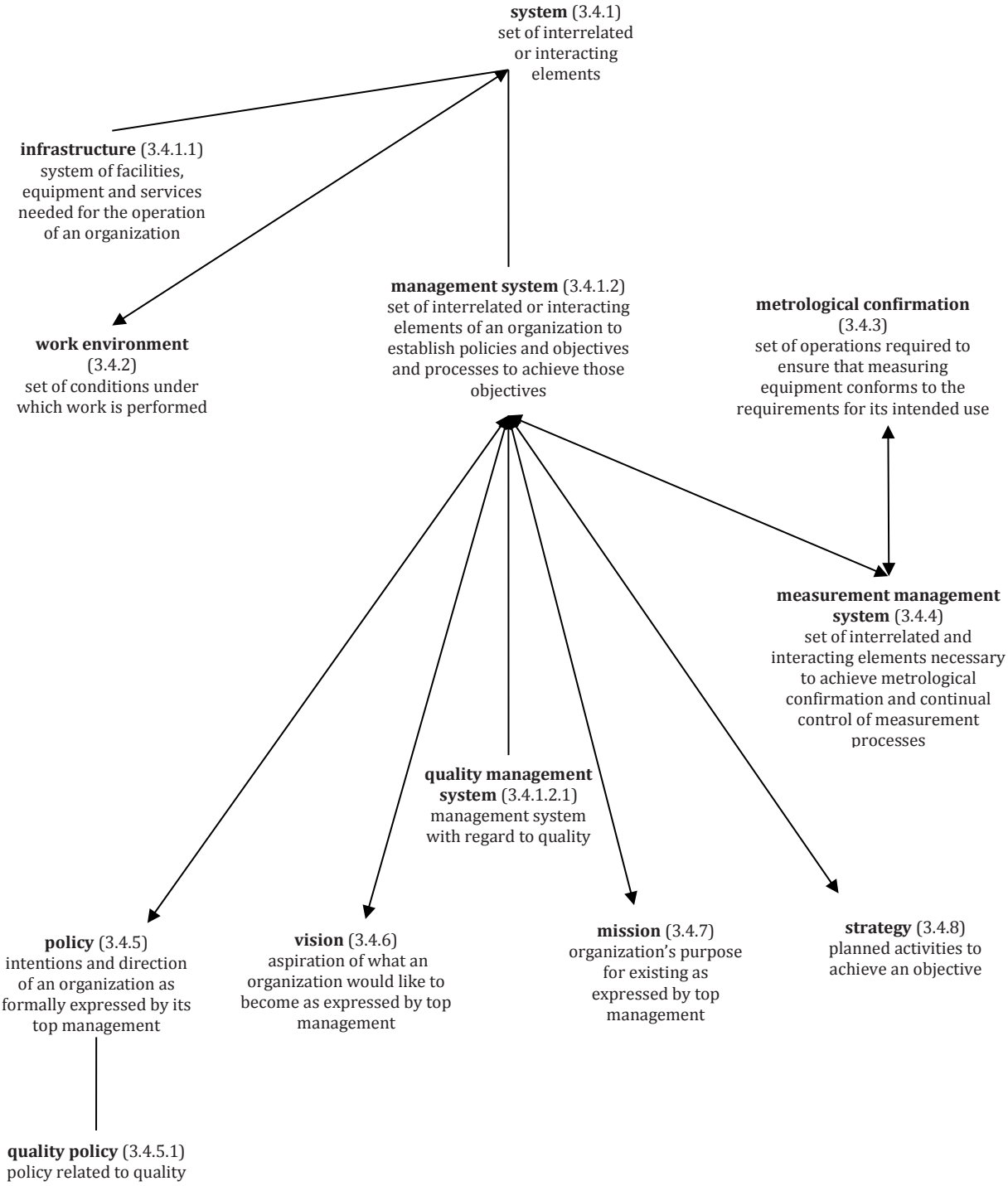

Figure A.7 – 3.4 Concepts of the class system and related concepts
For more information see notes in Clause 3

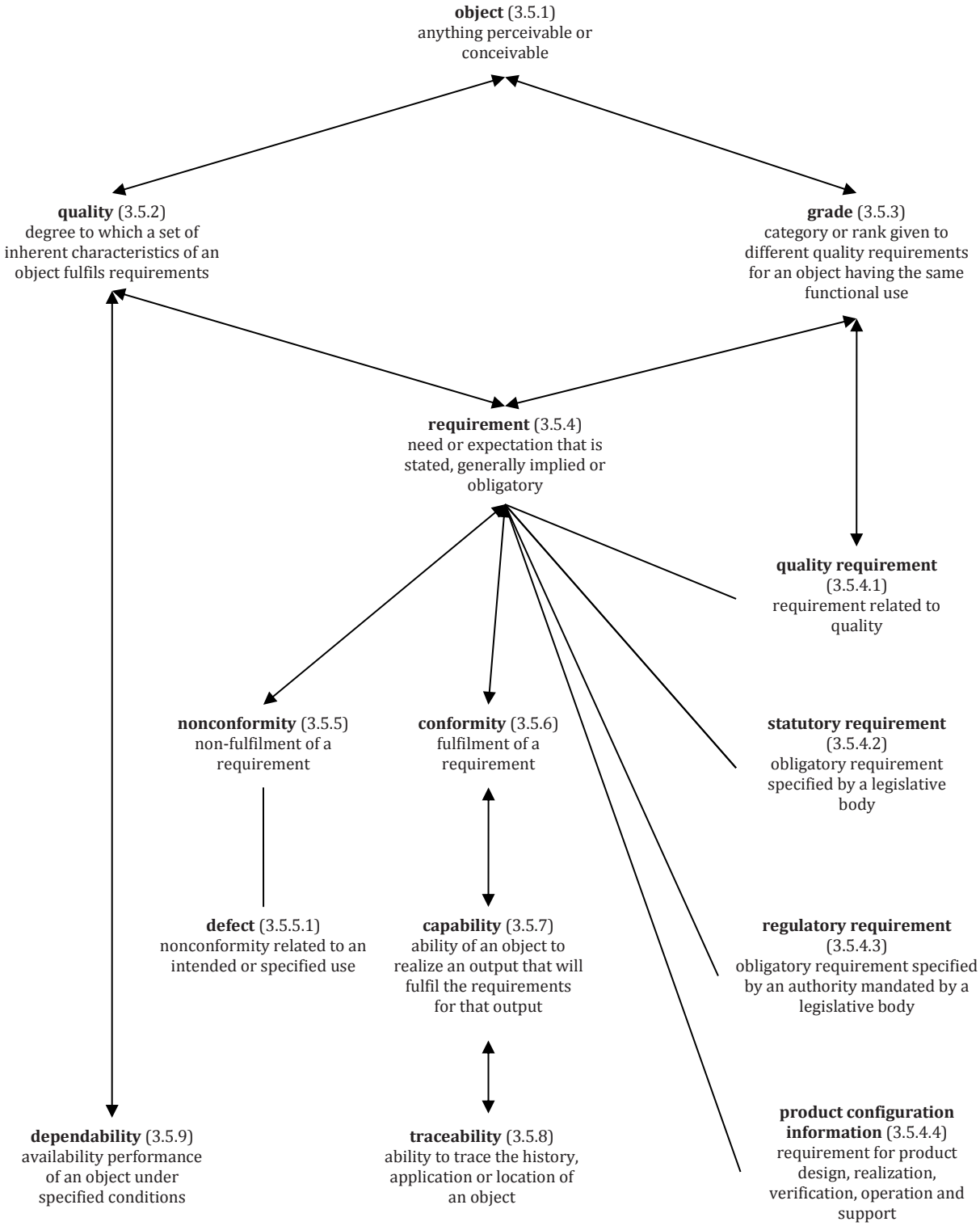

Figure A.8 – 3.5 Concepts of the class requirement and related concepts
For more information see notes in Clause 3

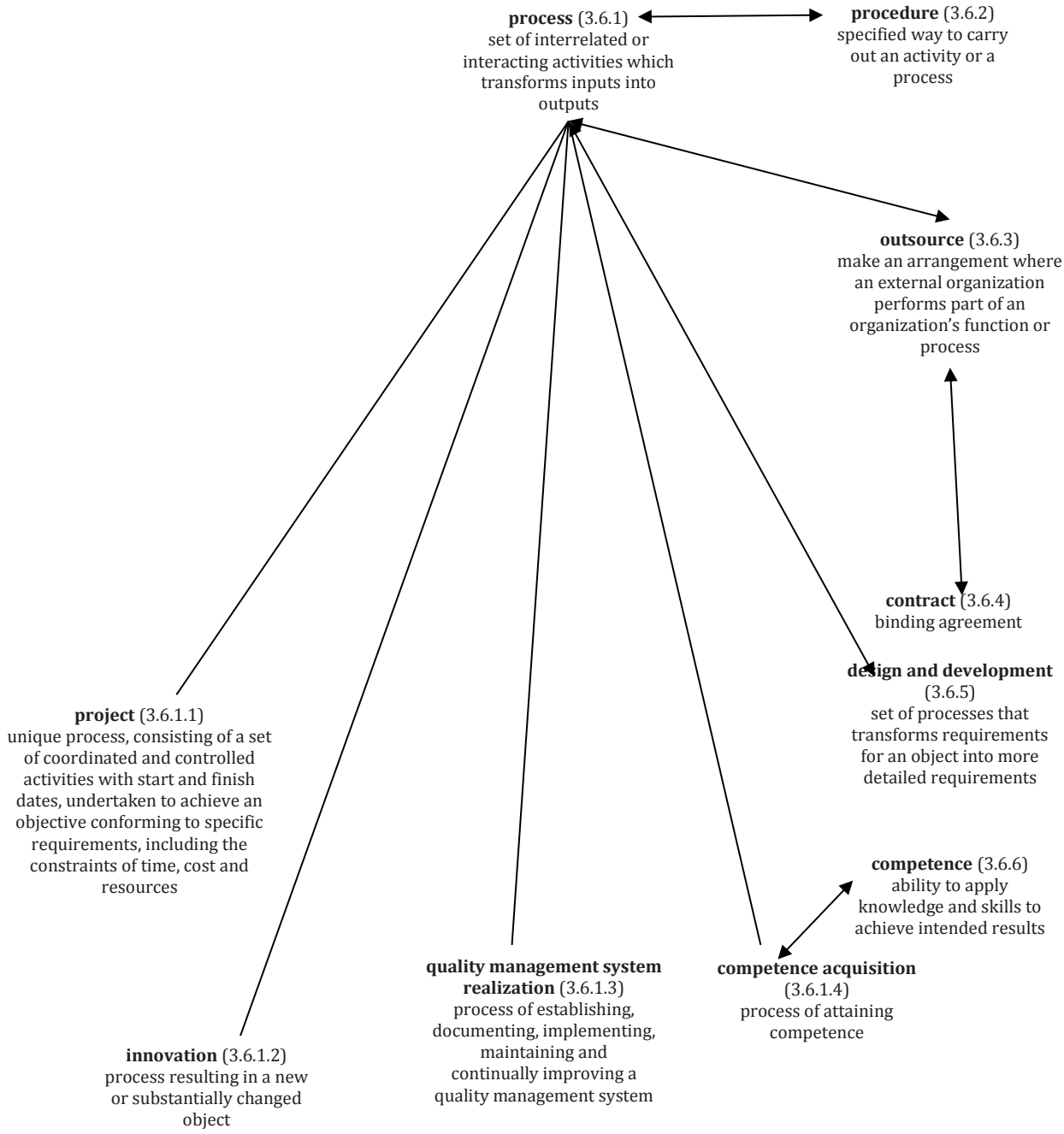

Figure A.9 – 3.6 Concepts of the class process and related concepts
For more information see notes in Clause 3

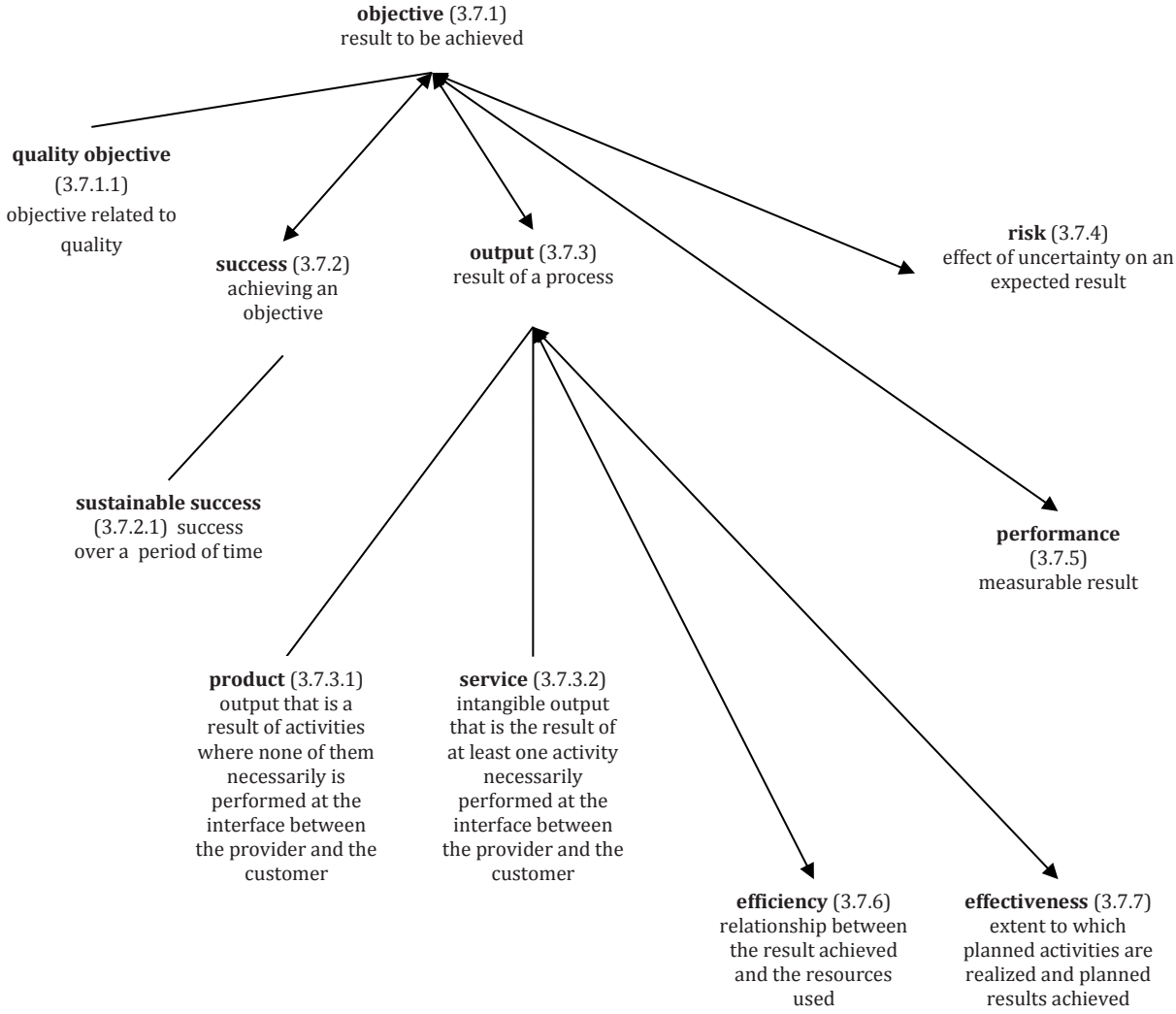

Figure A.10 — 3.7 Concepts related to results and related concepts
For more information see notes in Clause 3

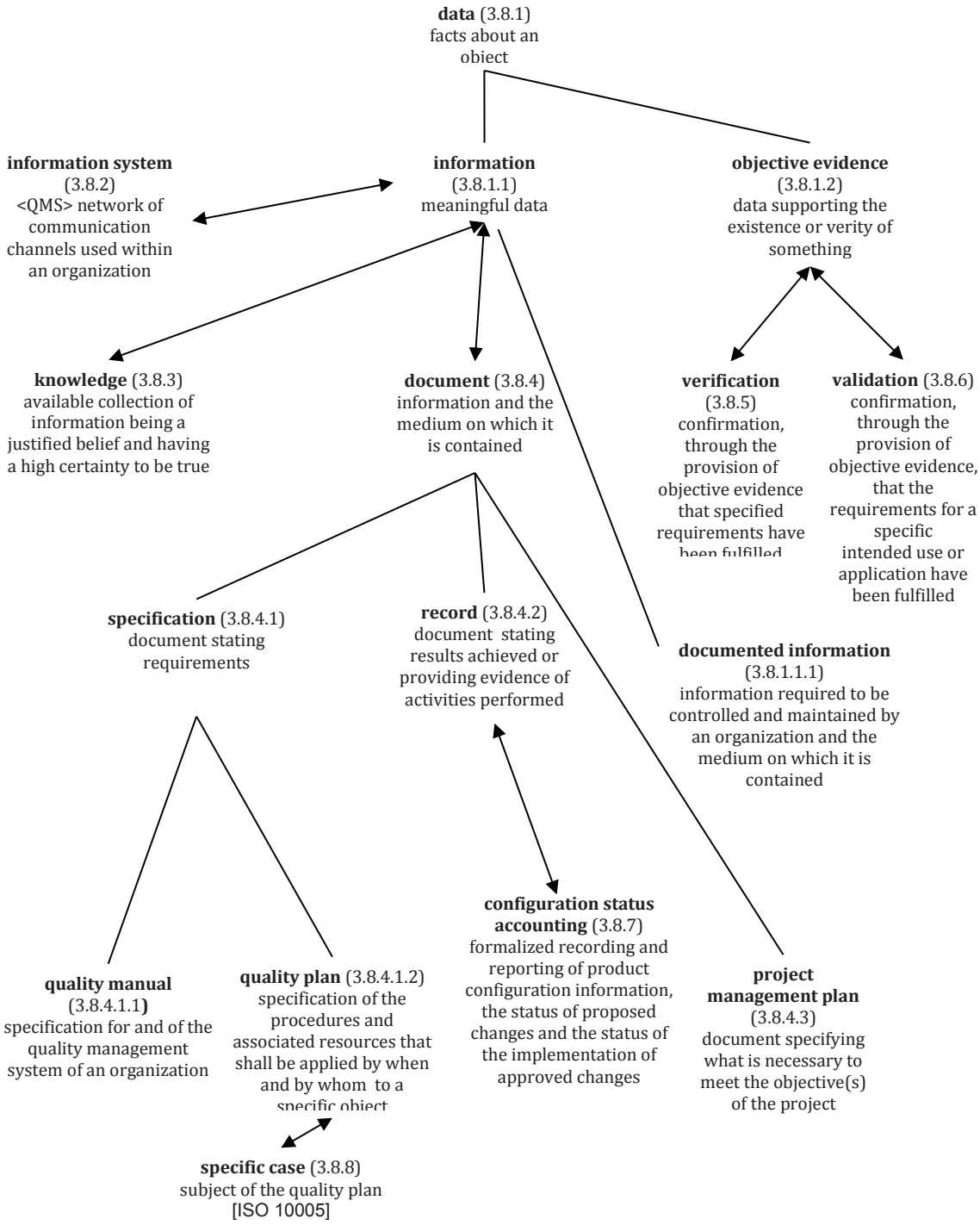

Figure A.11 — 3.8 Concepts of the classes data, information and document and related concepts
For more information see notes in Clause 3

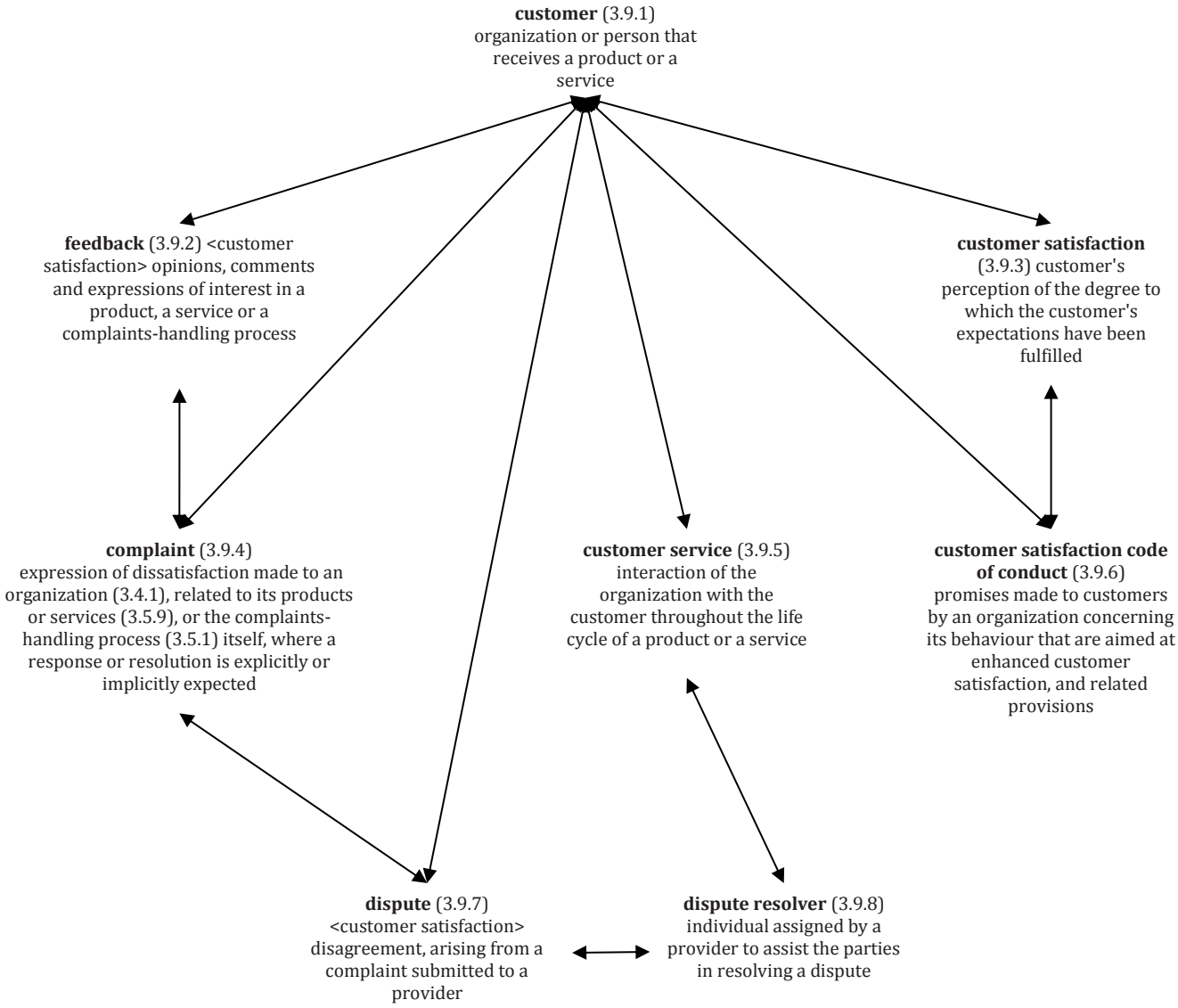

Figure A.12 — 3.9 Concepts related to customer and related concepts
For more information see notes in Clause 3

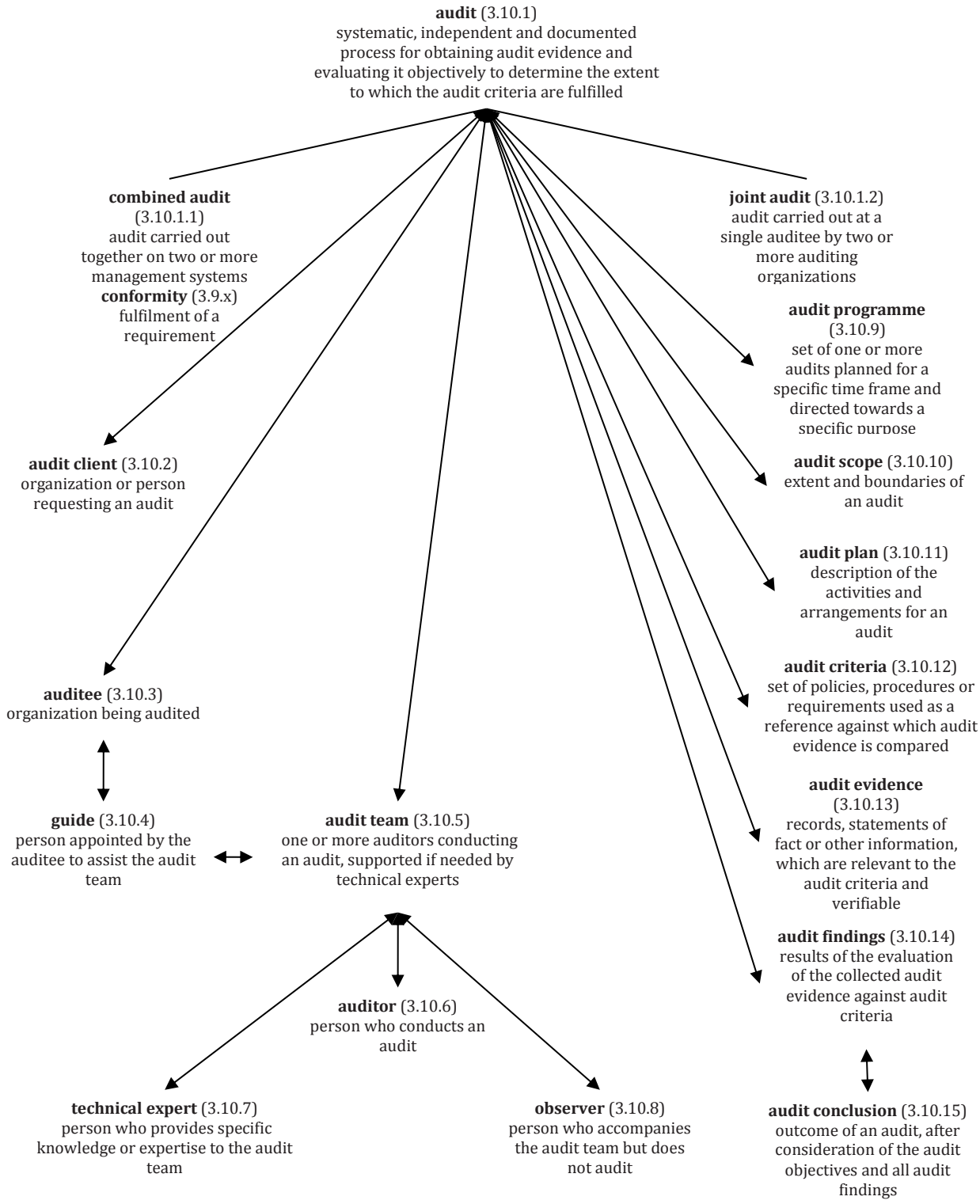

Figure A.13 — 3.10 Concepts related to audit and related concepts
For more information see notes in Clause 3

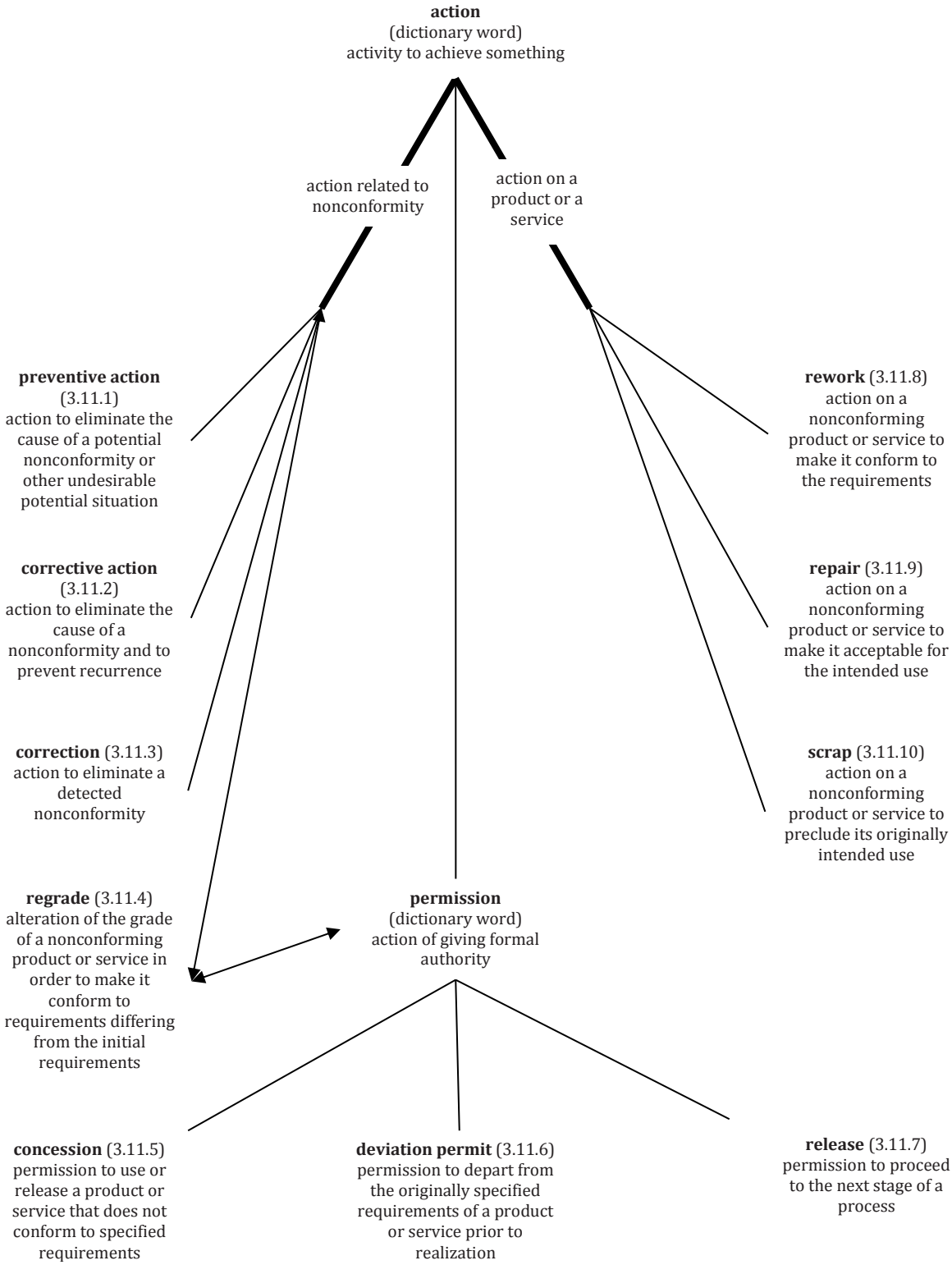

Figure A.14 – 3.11 Concepts of the class action and related concepts
For more information see notes in Clause 3

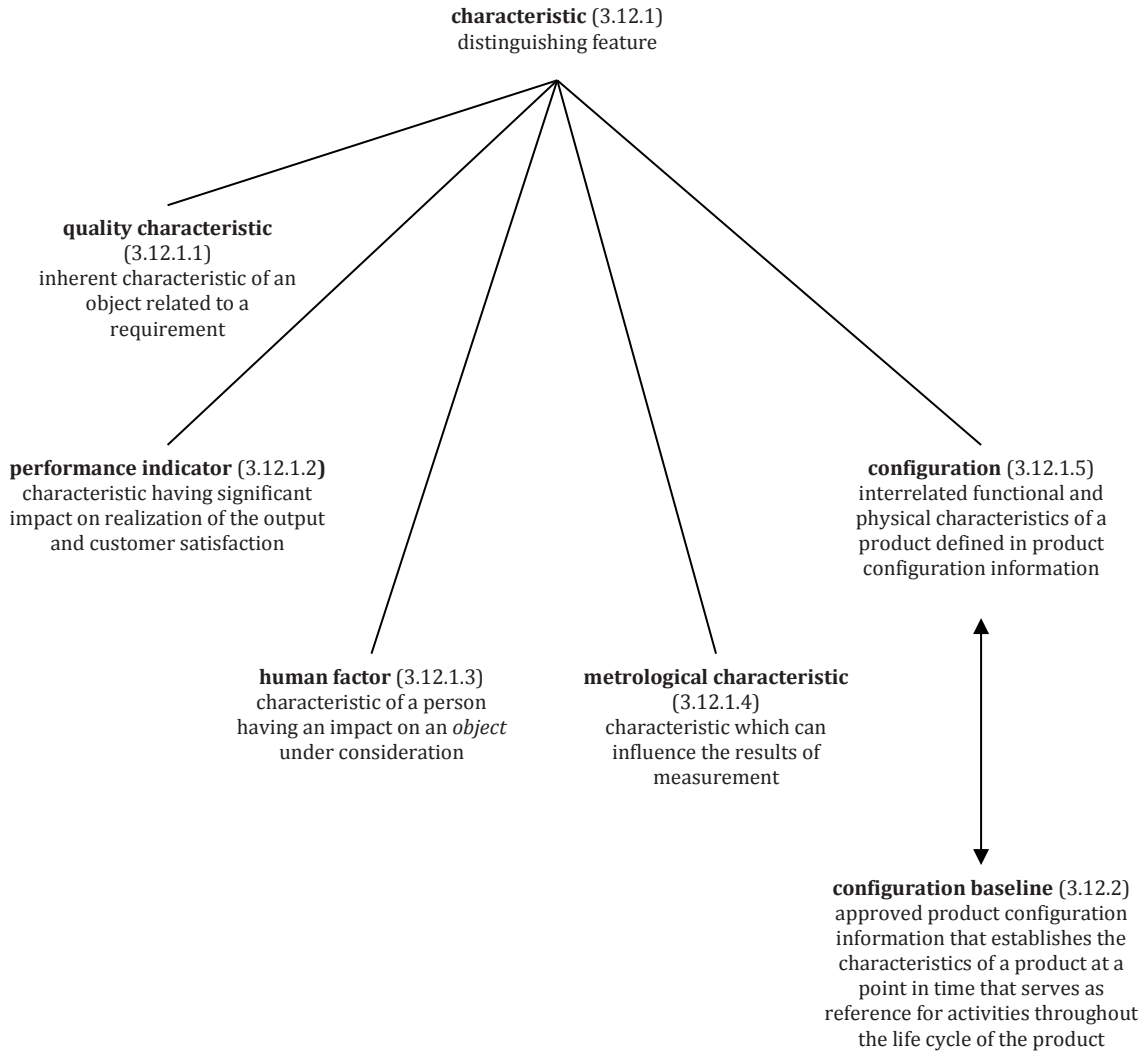

Figure A.15 — 3.12 Concepts of the class characteristic
For more information see notes in Clause 3

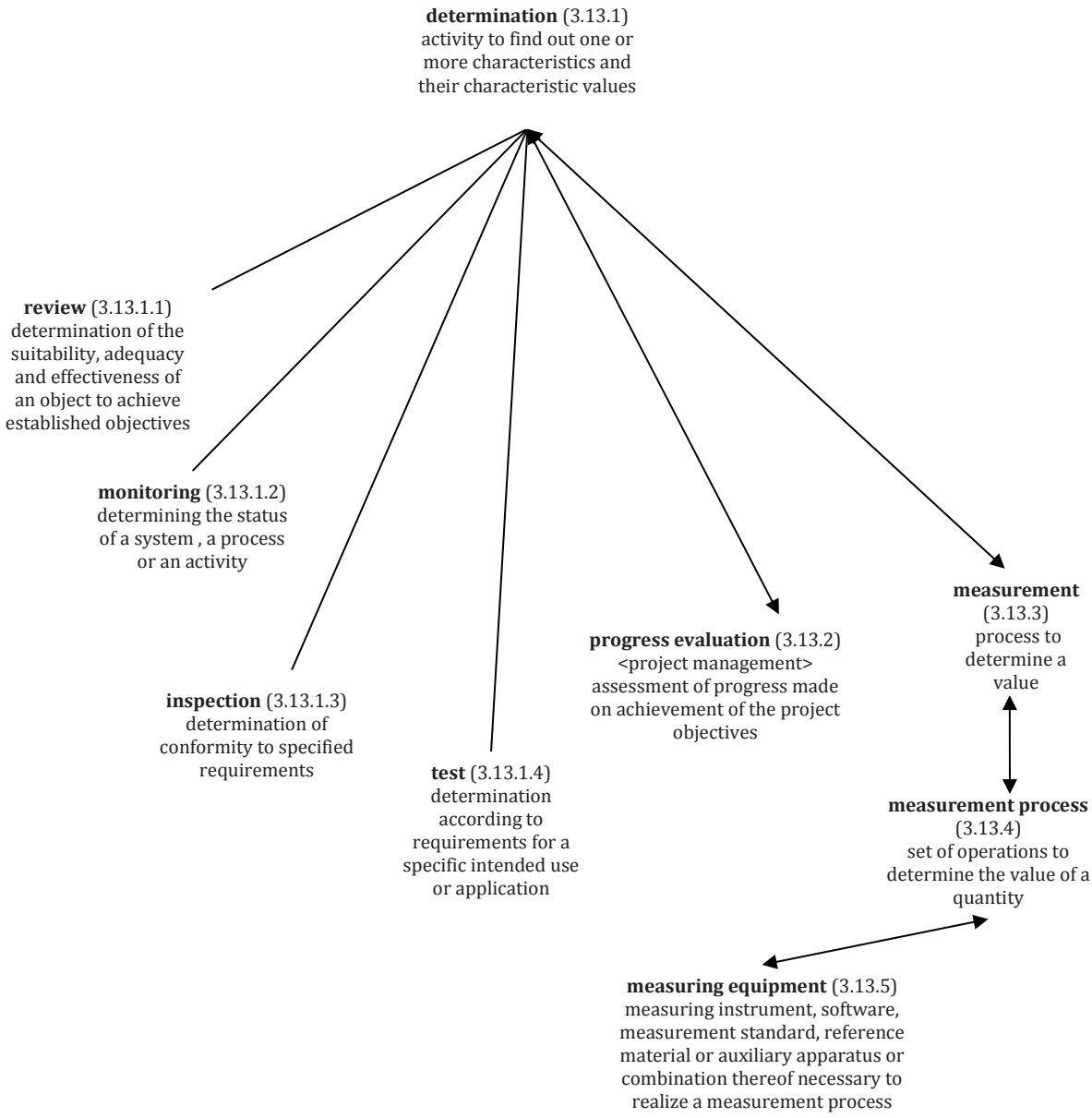

Figure A.16 — 3.13 Concepts of the class determination and related concepts
For more information see notes in Clause 3

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